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Presidential Documents

Title 3—

The President

Proclamation 10427 of July 26, 2022

National Korean War Veterans Armistice Day, 2022

By the President of the United States of America

A Proclamation

In June of 1950, the United States answered the call to defend freedom abroad by joining the Republic of Korea in its fight against the communist regime in North Korea and eventually the People's Republic of China. After 3 years of violent combat across the Korean peninsula, an armistice was signed by representatives of the United States as head of the United Nations Command, the People's Republic of China, and North Korea. For nearly 70 years, the ensuing peace and the abiding relationship between the Korean and American people has been the foundation for the thriving democracy and incredible economic progress of the Republic of Korea. During my recent visit to the Republic of Korea, I paid tribute to those Korean troops who fought and sacrificed shoulder-to-shoulder with Americans, along with our United Nations counterparts, to defend their country. Today, our Nation honors those selfless American service members whose courage and sacrifice helped forge the armistice, the enduring Alliance between our two nations, and a lasting legacy of freedom in the Republic of Korea.

Today, the Republic of Korea is our strong ally, a global center of innovation, and a vibrant democracy. In Seoul, I affirmed with President Yoon that the U.S.-ROK Alliance is stronger than ever, evolving to maintain its role as a linchpin of peace and stability in the region and increasingly expanding to the global stage. At Osan Air Base, I met with some of the brave American troops and their families who are stationed in the Republic of Korea, still serving side-by-side with our South Korean allies and strengthening the bonds between our people.

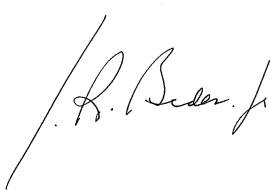
During the Korean War, nearly 1.8 million Americans answered the call to serve and defend the freedoms and universal values that the people of South Korea enjoy today. They faced enormous challenges—often outnumbered by the enemy, facing extreme heat and cold while fighting in the mountains and valleys and in the rice paddies and rocky terrain of the Korean Peninsula. More than 36,000 of those American service members were killed in action, along with more than 7,000 Korean Augmentation to the United States Army soldiers that fought with the United States Armed Forces—sacrificing everything to defend freedom and democracy on the Peninsula. Thousands were held in brutal captivity. Thousands remain unaccounted for to this day. Many more service members returned home with wounds of war, both visible and invisible. The First Lady and I are committed to fully accounting for all of our Prisoners of War and Missing in Action and fulfilling our sacred obligation to care for our veterans and their families, caregivers, and survivors, making sure they receive the benefits and services they have earned.

Today and every day, we continue to remember our Nation's Korean War Veterans and honor all that they made possible through service to our Nation and our highest ideals.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 27, 2022, as National Korean War Veterans Armistice Day. On this day, I encourage

all Americans to reflect on the strength, sacrifices, and sense of duty of our Korean War Veterans and bestow upon them the high honor they deserve. I call upon all Americans to observe this day with appropriate ceremonies and activities that honor and give thanks to our distinguished Korean War Veterans.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of July, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2022–16446
Filed 7–28–22; 8:45 am]
Billing code 3395–F2–P

Presidential Documents

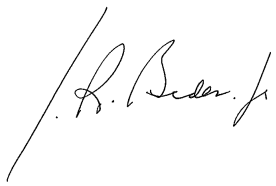
Memorandum of July 22, 2022

Delegation of Authority Under Section 506(a)(1) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(1) of the FAA to direct the drawdown of up to $175 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Ukraine and to make the determinations required under such section to direct such a drawdown.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2022

[FR Doc. 2022–16447
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Billing code 4710–10–P

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1075; Project Identifier MCAI–2021–00856–T; Amendment 39–22077; AD 2022–12–05]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–26–01, which applied to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. AD 2020–26–01 required repetitive general visual inspections of the affected main landing gear (MLG) sliding tubes for cracks, and replacement if necessary. This AD was prompted by reports of cracks found on MLG sliding tubes that may have been subject to improperly performed magnetic particle inspection. This AD requires repetitive general visual inspections of the affected MLG sliding tubes (both retained affected parts and additional affected parts) for cracks, and replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also adds airplanes to the applicability. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 2, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 2, 2022.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0175, dated July 22, 2021; corrected July 23, 2021 (EASA AD 2021–0175) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232, A320–233, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020) (AD 2020–26–01). AD 2020–26–01 applied to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. The NPRM published in the **Federal Register** on December 27, 2021 (86 FR 73197). The NPRM was prompted by reports of cracks found on MLG sliding tubes that may have been subject to improperly performed magnetic particle inspection. The NPRM proposed to require repetitive general visual inspections of the affected MLG sliding tubes (both retained affected parts and additional affected parts) for cracks, and replacement if necessary, as specified in EASA AD 2021–0175. The NPRM also proposed to add airplanes to the applicability.

The FAA is issuing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

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

The FAA also received a comment from Delta Air Lines (DAL). The following presents the comment received on the NPRM and the FAA's response.

Request for Clarification of Inspection Requirements

DAL requested clarification of the language specified in paragraph (6) of EASA AD 2021–0175 that ''following installation, the part is inspected as required by this [EASA] AD.'' DAL stated that more than one interpretation is possible, but it presumed the intent to be that an affected part can only be

installed if it is inspected within the compliance time specified in paragraph (1) of EASA AD 2021–0175 (rather than requiring an inspection immediately after installing an affected part on-wing).

The FAA agrees to clarify the referenced quote. The statement ''following installation, the part is inspected as required by this [EASA] AD'' does not mean an inspection is required before further flight after installing an affected part. Instead, it means that the part must meet the inspection requirements of paragraph (1) of EASA AD 2021–0175 at the applicable compliance times specified in paragraph (1) of EASA AD 2021–0175.

Conclusion

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

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0175 describes procedures for repetitive general visual inspections of the MLG sliding tubes for cracks, and replacement if necessary. EASA AD 2021–0175 also describes terminating actions for the repetitive inspections of affected MLG sliding tubes by either overhauling an affected MLG sliding tube or replacing an affected MLG sliding tube with an MLG sliding tube that is not affected.

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

Costs of Compliance

The FAA estimates that this AD affects 1,524 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2020–26–01.	2 work-hours × $85 per hour = $170	$0	$170	$259,080
New proposed actions	2 work-hours × $85 per hour = $170	0	170	259,080

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
19 work-hours × $85 per hour = $1,615	$185	$1,800

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020); and

■ b. Adding the following new AD:

2022–12–05 Airbus SAS: Amendment 39–22077; Docket No. FAA–2021–1075; Project Identifier MCAI–2021–00856–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 2, 2022.

(b) Affected ADs

This AD replaces AD 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020) (AD 2020–26–01).

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by reports of cracks found on main landing gear (MLG) sliding tubes that may have been subject to improperly performed magnetic particle inspection. The FAA is issuing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0175, dated July 22, 2021; corrected July 23, 2021 (EASA AD 2021–0175).

(h) Exceptions to EASA AD 2021–0175

(1) Where EASA AD 2021–0175 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2021–0175 refers to July 10, 2018 (the effective date of EASA AD 2018–0136, dated June 26, 2018), this AD requires using April 9, 2019 (the effective date of AD 2019–03–18, Amendment 39–19570 (84 FR 7804, March 5, 2019)).

(3) Where EASA AD 2021–0175 refers to December 2, 2020 (the effective date of EASA AD 2020–0258, dated November 18, 2020; corrected November 19. 2020), this AD requires using January 4, 2021 (the effective date of AD 2020–26–01).

(4) Where paragraph (1) of EASA AD 2021–0175 specifies compliance times to do the initial inspection, for this AD, the initial inspection must be done within the applicable compliance time specified in paragraph (1) of EASA AD 2021–0175, or within 30 days after the effective date of this AD, whichever occurs later.

(5) The ''Remarks'' section of EASA AD 2021–0175 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0175 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

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

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

(k) Related Information

For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email *vladimir.ulyanov@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2021–0175, dated July 22, 2021; corrected July 23, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0175, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

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

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

Issued on June 4, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–16101 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0976; Project Identifier AD–2022–00722–T; Amendment 39–22130; AD 2022–16–01]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–08–07, which applied to all Embraer S.A. Model ERJ 170–100 STD, –100 LR, –100 SU, and –100 SE airplanes; Model ERJ 170–200 STD, –200 LR, and –200 SU airplanes; Model ERJ 190–100 STD, –100 LR, –100 IGW, and –100 ECJ airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes. AD 2022–08–07 required determining if certain NORDAM passenger windows are installed, inspecting affected parts for cracks, and replacing cracked parts. AD 2022–08–07 also required repetitive inspections of uncracked affected parts until all affected parts are replaced. This

AD was prompted by a determination that additional airplanes are affected by the unsafe condition identified in AD 2022–08–07. This AD retains certain requirements of AD 2022–08–07, revises the applicability of AD 2022–08–07 to include the affected parts for clarification, and adds a certain airplane model to the applicability. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 15, 2022.

The FAA must receive comments on this AD by September 12, 2022.

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

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

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0976; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2022–08–07, Amendment 39–22010 (87 FR 21003, April 11, 2022) (AD 2022–08–07), for all Embraer S.A. Model ERJ 170–100 STD, –100 LR, –100 SU, and –100 SE airplanes; Model ERJ 170–200 STD, –200 LR, and –200 SU airplanes; Model ERJ 190–100 STD, –100 LR, –100 IGW, and –100 ECJ airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes. AD 2022–08–07 required determining if certain NORDAM passenger windows are installed (*i.e.,* windows having parts manufacturer approval (PMA) part number (P/N) NP00038–3), inspecting affected parts for cracks, and replacing cracked parts. AD 2022–08–07 also required repetitive inspections of uncracked affected parts until all affected parts are replaced. AD 2022–08–07 also prohibited the installation of affected parts. AD 2022–08–07 was prompted by a report of the failure of the inner pane of the passenger window to meet maximum operating pressure and lack of fail-safe design. The FAA issued AD 2022–08–07 to address this condition, which could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight and landing of the airplane.

Actions Since AD 2022–08–07 Was Issued

Since the FAA issued AD 2022–08–07, the agency has determined that Model ERJ 170–200 LL airplanes are also affected by the identified unsafe condition. For Model ERJ 170–200 LR airplanes that were converted to Model ERJ 170–200 LL airplanes, the affected parts could be installed on one of the converted airplanes. The FAA also determined that, for clarity, the applicability of AD 2022–08–07 must be revised to include the affected parts.

Comments on AD 2022–08–07

The FAA issued AD 2022–08–07 as a final rule; request for comments. The FAA received a comment from Aerolitoral, S.A. de C.V. (Aeromexico Connect) who expressed support for AD 2022–08–07. The FAA received additional comments from five commenters, including Agência Nacional de Aviação Civil (ANAC), Embraer, Myanmar Airways International, Servicio Aéreo a Territorios Nacionales (SATENA), and Ukraine International Airlines. The FAA determined that certain comments contained information to warrant changes to AD 2022–08–07. The following presents the comments received on AD 2022–08–07 and the FAA's response to each comment.

Request To Revise Applicability

Embraer requested that the FAA revise the applicability in paragraph (c) of AD 2022–08–07 to specify that the AD applies to NORDAM passenger windows having PMA P/N NP00038–3 and that the part could be installed on the airplanes identified in paragraphs (c)(1) through (4) of AD 2022–08–07. Embraer stated that the applicability of AD 2022–08–07 specifies that certain airplanes are affected; however, Embraer noted the AD should specify it is applicable to the PMA passenger windows. Embraer stated the applicability is generating questions and doubts from operators and local authorities in countries where PMA part numbers are not approved by local regulators. Embraer noted it is unable to define if the AD is applicable or not to specific operators as it depends on the local aircraft civil operations rules.

ANAC, which is the aviation authority for Brazil, also requested that the FAA revise the applicability to make it clear the AD is component-level AD and not an airplane-level AD. ANAC stated that if the affected parts can be used on any airplane registered outside of the U.S., it is concerned that other countries may not follow the AD, as the FAA is not the State of Design Authority for the airplanes.

The FAA agrees to revise the applicability and has revised paragraph (c) of this AD to specify this AD applies to airplanes equipped with NORDAM passenger windows having PMA P/N NP00038–3. As noted, the FAA is not the State of Design Authority for Embraer airplanes. However, the FAA is responsible for the affected PMA part. The change to the applicability clarifies this AD is applicable to the affected PMA parts, which are only installed on the Embraer airplanes identified in the applicability. The change to the applicability does not change how the unsafe condition is addressed. All affected PMA parts must be inspected and replaced as required by this AD.

Request To Clarify Affected Parts

Embraer requested that the FAA clarify paragraph (g) of AD 2022–08–07 to specify that the affected part is a PMA part. Embraer stated that NORDAM P/N NP00038–3 is a PMA part number that is not part of the Embraer type design since it is an FAA-approved PMA part number.

The FAA agrees to clarify that the affected parts are PMA parts and has revised paragraphs (g) and (j) of this AD accordingly. The FAA also notes that the NORDAM PMA part number is distinct from the original equipment manufacturer (Embraer) part number and has added Note 1 to paragraph (c) of this AD to clarify that the Embraer part number is not affected by this AD.

Request To Clarify Part Number

Ukraine International Airlines and SATENA requested that the FAA clarify the affected part number. The commenters stated that the illustrated

parts catalog (IPC) for Embraer 190 does not mention the part number specified in AD 2022–08–07. Ukraine International Airlines stated the IPC lists a ''TRANSPARENCY, PAX WINDOW'' having P/N P00038–3 only (without the letter ''N'' before the number).

The FAA agrees to clarify. NORDAM manufactures P/N NP00038–3 as a PMA replacement part for the original equipment manufacturer (Embraer) P/N P00038–3. As specified in paragraph (c) of this AD, this AD only applies to the NORDAM PMA part number, not the original Embraer part number.

Request for Contact Information

Myanmar Airways International requested that the FAA provide contact information for the NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022, referenced in AD 2022–08–07. The commenter noted that the NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022, is referred to as guidance for accomplishing the actions.

The FAA agrees for the reasons provided. The FAA has included contact information for obtaining a copy of NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022, in paragraph (o)(2) of this AD.

FAA's Determination

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

AD Requirements

This AD requires repetitive inspections of NORDAM passenger windows having PMA P/N NP00038–3 for cracks, replacement of cracked windows, and eventual replacement of all PMA P/N NP00038–3 windows. This AD also prohibits the installation of PMA P/N NP00038–3 windows.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because due to the lack of a fail-safe design and failure of the window's inner pane to meet maximum operating pressure, a complete failure of the outer window pane could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight and landing of the airplane. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0976 and Project Identifier AD–2022–00722–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 65 airplanes of U.S. registry (only a total of 65 affected parts were produced). The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections for cracking (retained action from AD 2022–08–07).	Up to 1 work-hour × $85 per hour = $85 per inspection cycle.	$0	$85 per inspection cycle.	Up to $5,525 per inspection cycle.
Replacement (retained action from AD 2022–08–07).	2 work-hours × $85 per hour = $170	500	$670	Up to $43,550.

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections for cracking (new action for added airplane model).	Up to 1 work-hour × $85 per hour = $85 per inspection cycle.	0	$85 per inspection cycle.	Up to $5,525 per inspection cycle.
Replacement (new action for added airplane model).	2 work-hours × $85 per hour = $170	500	$670	Up to $43,550.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	2 work-hours × $85 per hour = $170	$500	$670

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–08–07, Amendment 39–22010 (87 FR 21003, April 11, 2022); and

■ b. Adding the following new AD:

2022–16–01 Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.): Amendment 39–22130; Docket No. FAA–2022–0976; Project Identifier AD–2022–00722–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 15, 2022.

(b) Affected ADs

This AD replaces AD 2022–08–07, Amendment 39–22010 (87 FR 21003, April 11, 2022) (AD 2022–08–07).

(c) Applicability

This AD applies to all Embraer S.A. airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category; equipped with any NORDAM passenger window having parts manufacturer approval (PMA) part number (P/N) NP00038–3.

Note 1 to the introductory text of paragraph (c): PMA P/N NP00038–3 is approved for type design (Embraer) P/N P00038–3. Only PMA P/N NP00038–3 is affected by this AD.

(1) Model ERJ 170–100 STD, –100 LR, –100 SU, and –100 SE airplanes.

(2) Model ERJ 170–200 STD, –200 LR, –200 SU, and –200 LL airplanes.

(3) Model ERJ 190–100 STD, –100 LR, –100 IGW, and –100 ECJ airplanes.

(4) Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 56, Windows.

(e) Unsafe Condition

This AD was prompted by a report of the failure of the inner pane of the passenger window to meet maximum operating pressure and lack of fail-safe design, and by a determination that additional airplanes are affected by the unsafe condition identified in AD 2022–08–07. The FAA is issuing this AD to address this condition, which could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight and landing of the airplane.

(f) Compliance

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

(g) Retained Definition of Affected Parts With a Clarification That the Affected Parts Are PMA Parts

This paragraph restates the definition specified in paragraph (g) of AD 2022–08–07, with a clarification that the affected parts are PMA parts. For the purposes of this AD, affected parts are NORDAM passenger

windows having PMA part number (P/N) NP00038–3.

(h) Retained Inspections and Replacement With Added Reference to Affected Parts in Paragraph (h)(1) of This AD

This paragraph restates the requirements of paragraphs (h)(1) and (2) of AD 2022–08–07, with added reference to affected parts in paragraph (h)(1) of this AD. For all airplanes except Model ERJ 170–200 LL airplanes, comply with the actions required by paragraphs (h)(1) and (2) of this AD.

(1) Before further flight, do a visual inspection of the outer window pane of the affected parts for cracking, and do the applicable action specified in paragraph (h)(1)(i) or (ii) of this AD.

(i) If any cracking is found, before further flight, replace the affected part with a serviceable window.

(ii) If no cracking is found, repeat the inspection thereafter before each flight, until the affected part is replaced, as specified in paragraph (h)(2) of this AD.

(2) Within 90 days after April 26, 2022 (the effective date AD 2022–08–07): Replace all affected parts installed on the airplane with serviceable windows.

Note 2 to paragraph (h): Guidance for the actions required by paragraph (h) of this AD can be found in NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022.

(i) Retained Terminating Action for Repetitive Inspections Required by Paragraph (h)(1)(ii) of This AD With No Changes

This paragraph restates the terminating action specified in paragraph (i) of AD 2022–08–07, with no changes. Replacement of an affected part, as specified in paragraph (h)(2) of this AD, terminates the repetitive inspection requirements specified in paragraph (h)(1)(ii) of this AD for that part.

(j) Retained Parts Installation Prohibition With a Clarification That the Affected Parts Are PMA Parts

This paragraph restates the parts installation prohibition specified in paragraph (j) of AD 2022–08–07, with a clarification that the affected parts are PMA parts. For all airplanes except Model ERJ 170–200 LL airplanes: As of April 26, 2022 (the effective date AD 2022–08–07), no person may install a NORDAM passenger window, PMA P/N NP00038–3, on any airplane.

(k) New Inspections and Replacement for Certain Airplanes

For Model ERJ 170–200 LL airplanes: Comply with the actions required by paragraphs (k)(1) and (2) of this AD.

(1) Before further flight, do a visual inspection of the outer window pane of the affected parts for cracking, and do the applicable action specified in paragraph (k)(1)(i) or (ii) of this AD.

(i) If any cracking is found, before further flight, replace the affected part with a serviceable window.

(ii) If no cracking is found, repeat the inspection thereafter before each flight, until the affected part is replaced, as specified in paragraph (k)(2) of this AD.

(2) Within 90 days after the effective date of this AD: Replace all affected parts installed on the airplane with serviceable windows.

Note 3 to paragraph (k): Guidance for the actions required by paragraph (k) of this AD can be found in NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022.

(l) Terminating Action for Repetitive Inspections Required by Paragraph (k)(1)(ii) of This AD

Replacement of an affected part, as specified in paragraph (k)(2) of this AD, terminates the repetitive inspection requirements specified in paragraph (k)(1)(ii) of this AD for that part.

(m) New Parts Installation Prohibition for Certain Airplanes

For Model ERJ 170–200 LL airplanes: As of the effective date of this AD, no person may install a NORDAM passenger window, PMA P/N NP00038–3, on any airplane.

(n) Alternative Methods of Compliance (AMOCs)

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

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

(o) Related Information

(1) For more information about this AD, contact Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.*

(2) For service information identified in this AD that is not incorporated by reference, contact The NORDAM Group LLC, Transparency Division, 7018 North Lakewood Ave., Tulsa, OK 74117; email John Clawson, Vice President Engineering and Program Management, NORDAM Corporate Division, at *jclawson@nordam.com;* internet *https://nordam.com.*

(p) Material Incorporated by Reference

None.

Issued on July 21, 2022.

Christina Underwood,

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

[FR Doc. 2022–16361 Filed 7–27–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0983; Project Identifier AD–2022–00614–E; Amendment 39–22132; AD 2022–16–03]

RIN 2120–AA64

Airworthiness Directives; Continental Aerospace Technologies, Inc., Lycoming Engines, and Textron Lycoming/Subsidiary of Textron, Inc. Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Continental Aerospace Technologies, Inc. GTSIO–520, IO–346, IO–470, IO–520, IO–550, LTSIO–520, O–470, TSIO–520, and TSIOL–550 series model reciprocating engines, Lycoming Engines AEIO–320, AEIO–360, AEIO–540, AIO–320, AIO–360, GO–480, GSO–480, HIO–360, HIO–540, IGO–480, IGO–540, IGSO–480, IGSO–540, IO–320, IO–360, IO–540, LIO–360, LTIO–540, O–235, O–320, O–360, O–540, TIGO–541, TIO–360, TIO–540, TIO–541, TVO–435, VO–435, and VO–540 series model reciprocating engines, and Textron Lycoming/Subsidiary of Textron, Inc. IO–720 series model reciprocating engines. This AD was prompted by a report of a manufacturing quality escape of improperly lubricated roller bearings installed in certain magnetos, which may result in overheating and magneto seizure. This AD requires the replacement of affected magneto or inspection of affected magneto and, if no white grease is detected, replacement of magneto components, as applicable, and reassembly of the magneto. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 15, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 15, 2022.

The FAA must receive comments on this AD by September 12, 2022.

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

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.

• *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Continental Aerospace Technologies, P.O. Box 90, Mobile, AL 36615; phone: (251) 436–8299; website: *www.continental.aero.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0983; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Boyce Jones, Aviation Safety Engineer, Atlanta ACO, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5535; email: *boyce.jones@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA received a report from Continental Aerospace Technologies, Inc., of a manufacturing quality escape that identified a certain population of magnetos that did not meet the design specification due to improperly lubricated roller bearings. The supplier notified the manufacturer that roller bearings installed in certain magnetos were delivered with a light corrosion preventive lubricant instead of the specified translucent white grease. Analysis by the manufacturer determined that affected magnetos assembled without the properly lubricated roller bearing have the potential to overheat, causing accelerated wear in the contact and cam follower. As a result of its analysis, the manufacturer published service information that specifies procedures for the removal and replacement of the affected magneto or inspection of the affected magneto and, if no white grease is detected, replacement of magneto components, as applicable, and reassembly of the magneto. This condition, if not addressed, could result in failure of one or more engines, in-flight shutdown, and loss of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Continental Aerospace Technologies Critical Service Bulletin CSB673, Revision C, dated May 24, 2022 (the CSB). The CSB specifies procedures for removing and replacing affected magneto or inspecting affected magneto and, if no white grease is detected, replacing magneto components, as applicable, and reassembling the magneto. This CSB also specifies procedures for returning certain parts to the manufacturer for warranty replacement. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

AD Requirements

This AD requires the replacement of the affected magneto or inspection of the affected magneto and, if no white grease is detected, replacement of magneto components, as applicable, and reassembly of the magneto.

Clarification of Requirements

The CSB specifies procedures to return certain parts to the manufacturer for warranty replacement. However, this AD does not require returning parts to the manufacturer. The CSB also specifies to discard the roller bearing after the roller bearing has been pressed out of the magneto housing. This AD does not require discarding the roller bearing.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because affected magnetos assembled without properly lubricated roller bearings have the potential to overheat, causing accelerated wear in the contact and cam follower that could lead to seizure and failure of the magnetos. Since an engine may contain two affected magnetos, there is a possibility of failure of one or more engines and loss of the airplane due to loss of ignition. The FAA considers replacement or inspection of the affected magneto to be an urgent safety issue. Replacement or inspection of the affected magneto must be accomplished within 25 operating hours time-in-service (TIS) or, if any affected magneto has accumulated more than 25 operating hours TIS, before further flight after the effective date of this AD. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''FAA–2022–0983 and Project Identifier AD–2022–00614–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Boyce Jones, Aviation Safety Engineer, Atlanta ACO, FAA, 1701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD could affect up to 740 magnetos installed on airplanes of U.S. registry. The FAA has no way of determining the number of operators that will remove the affected magneto and replace it with a part eligible for installation or, in lieu of replacing, disassemble, inspect and replace magneto components. The FAA's estimated cost on U.S. operators reflects the maximum possible cost based on the 740 affected magnetos installed on products of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove and replace the affected magneto.	1.5 work-hours × $85 per hour = $127.50	$1,600	$1,727.50	Up to $1,278,350.
Remove, disassemble, and inspect affected magneto.	1 work-hour × $85 per hour = $85	0	85	Up to $62,900.

The FAA estimates the following costs to replace magneto components. The agency has no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace magneto components	.25 work-hours × $85 per hour = $21.25	$20	$41.25
Reassemble and install magneto	1 work-hour × $85 per hour = $85	0	170

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–16–03 Continental Aerospace Technologies, Inc., Lycoming Engines, and Textron Lycoming/Subsidiary of Textron, Inc. Reciprocating Engines:

Amendment 39–22132; Docket No. FAA–2022–0983; Project Identifier AD–2022–00614–E.

(a) Effective Date

This airworthiness directive (AD) is effective August 15, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to:

(1) Continental Aerospace Technologies, Inc. reciprocating engine models identified in Table 1 to paragraph (c) of this AD that are equipped with an S–1200 series magneto having a serial number (S/N) between F21EA057 and F21KA009R, inclusive, manufactured and sold between May and November 2021; and

(2) Lycoming Engines and Textron Lycoming/Subsidiary of Textron, Inc. reciprocating engine models identified in Table 2 to paragraph (c) of this AD that are equipped with an S–1200 series magneto authorized by Continental Aerospace Technologies, Inc. Parts Manufacturer Approval (PMA) Supplements 1–54, having an S/N between F21EA057 and F21KA009R, inclusive, manufactured and sold between May and November 2021.

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Table 1 to Paragraph (c) – Continental Aerospace Technologies, Inc. Reciprocating Engine Models

Make	Model
Continental Aerospace Technologies, Inc.	GTSIO-520-C, GTSIO-520-D, GTSIO-520-F, GTSIO-520-H, GTSIO-520-K, GTSIO-520-L, GTSIO-520-M, GTSIO-520-N, IO-346-A, IO-470-C, IO-470-D, IO-470-E, IO-470-F, IO-470-G, IO-470-H, IO-470-J, IO-470-K, IO-470-L, IO-470-M, IO-470-N, IO-470-P, IO-470-R, IO-470-S, IO-470-U, IO-470-V, IO-470-VO, IO-520-A, IO-520-B, IO-520-BA, IO-520-BB, IO-520-C, IO-520-CB, IO-520-D, IO-520-E, IO-520-F, IO-520-J, IO-520-K, IO-520-L, IO-520-P, IO-550-B, IO-550-C, IO-550-D, IO-550-E, IO-550-F, IO-550-L, LTSIO-520-AE, O-470-B, O-470-E, O-470-G, O-470-J, O-470-K, O-470-L, O-470-M, O-470-R, O-470-S, O-470-U, TSIO-520-A, TSIO-520-AE, TSIO-520-AF, TSIO-520-B, TSIO-520-BB, TSIO-520-C, TSIO-520-CE, TSIO-520-DB, TSIO-520-G, TSIO-520-H, TSIO-520-KB, TSIO-520-LB, TSIO-520-M, TSIO-520-NB, TSIO-520-P, TSIO-520-R, TSIO-520-T, TSIO-520-UB, TSIO-520-VB, TSIO-520-WB, TSIOL-550-A, TSIOL-550-B, TSIOL-550-C

Table 2 to Paragraph (c) – Lycoming Engines and Textron Lycoming Reciprocating Engine Models

Make	Model
Lycoming Engines	AEIO-320-D1B, AEIO-320-D2B, AEIO-360-A1B, AEIO-360-A1B6, AEIO-360-A2B, AEIO-360-B1F, AEIO-360-B2F, AEIO-360-B2F6, AEIO-540-D4B5, AIO-320-A1A, AIO-320-A1B, AIO-320-A2A, AIO-320-A2B, AIO-320-B1B, AIO-320-C1B, AIO-360-A1A, AIO-360-A1B, AIO-360-A2A, AIO-360-A2B, AIO-360-B1B, GO-480-G1J6, GSO-480-B1J6, HIO-360-C1B, HIO-360-D1A, HIO-540-A1A, IGO-480-A1A6, IGO-540-A1C, IGSO-480-A1G6, IGSO-540-A1A, IGSO-540-A1C, IGSO-540-A1D, IGSO-540-A1E, IGSO-540-A1F, IGSO-540-A1H, IGSO-540-B1A, IGSO-540-B1C, IO-320-B1D, IO-320-B1E, IO-320-D1A, IO-320-D1B, IO-320-D1C, IO-360-A1B, IO-360-A1B6, IO-360-A1C, IO-360-A1D6, IO-360-A2B, IO-360-A2C, IO-360-B1E, IO-360-B1F, IO-360-B2E, IO-360-B2F, IO-360-B2F6, IO-360-C1B, IO-360-C1C, IO-360-C1C6, IO-360-C1D6, IO-360-C1E6, IO-360-C1F, IO-360-D1A, IO-360-E1A, IO-360-F1A, IO-540-B1A5, IO-540-D4B5, IO-540-D4C5, IO-540-E1B5, IO-540-E1C5, IO-540-G1B5, IO-540-G1C5, IO-540-G1D5, IO-540-G1E5, IO-540-G1F5, IO-540-J4A5, IO-540-K1A5, IO-540-K1B5, IO-540-K1C5, IO-540-K1D5, IO-540-K1E5, IO-540-K1F5, IO-540-K1G5, IO-540-K1H5, IO-540-K1J5, IO-540-K1K5, IO-540-L1A5, IO-540-L1C5, IO-540-M1A5, IO-540-M1C5, IO-540-P1A5, IO-540-R1A5, IO-540-S1A5, IO-540-T4B5, IO-540-W1A5, IO-540-AA1A5, LIO-360-C1E6, LTIO-540-J2B, LTIO-540-U2A, LTIO-540-W2A, O-235-C2B, O-235-E2B, O-235-F2B, O-235-G2B, O-235-J2B, O-235-K2B, O-320-D1C, O-320-D1F, O-320-D2C, O-320-D2F, O-320-E1C, O-320-E1F, O-320-E1J, O-320-E2C, O-320-E2F, O-360-A1F, O-360-A1F6, O-360-A1G, O-360-A1G6, O-360-A2F, O-360-A2G, O-360-A4G, O-360-C1F, O-540-B1D5, O-540-B2C5, O-540-E4C5, O-540-G1A5, O-540-G2A5, TIGO-541-B1A, TIGO-541-C1A, TIGO-541-D1A, TIGO-541-D1B, TIGO-541-E1A, TIO-360-A1A, TIO-360-A1B, TIO-540-A1A, TIO-540-A1B, TIO-540-A1C, TIO-540-A2A, TIO-540-A2B, TIO-540-A2C, TIO-540-C1A, TIO-540-E1A, TIO-540-G1A, TIO-540-H1A, TIO-540-J2B, TIO-540-U2A, TIO-540-W2A, TIO-541-A1A, TIO-541-E1A4, TIO-541-E1B4, TIO-541-E1C4, TIO-541-E1D4, TVO-435-B1B, TVO-435-D1A, TVO-435-F1A, TVO-435-G1A, VO-435-B1A, VO-540-B1H3, VO-540-B2G, VO-540-C2C
Textron Lycoming/Subsidiary of Textron, Inc.	IO-720-A1B, IO-720-B1B, IO-720-C1B

BILLING CODE 4910–13–C

(d) Subject

Joint Aircraft System Component (JASC) Code 8500, Engine (RECIPROCATING).

(e) Unsafe Condition

This AD was prompted by a report of a manufacturing quality escape of improperly lubricated roller bearings installed in certain magnetos, which may result in overheating and magneto seizure. The FAA is issuing this AD to prevent failure of the magneto. The unsafe condition, if not addressed, could result in failure of one or more engines, in-flight shutdown, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

For any affected magneto, within 25 operating hours time-in-service (TIS) or, if any affected magneto has accumulated more than 25 operating hours TIS, before further flight after the effective date of this AD:

(1) Remove the affected magneto from the engine and replace with a part eligible for installation in accordance with the Corrective Action, paragraph III.A., of Continental Aerospace Technologies Critical Service Bulletin CSB673, Revision C, dated May 24, 2022 (the CSB); or

(2) Remove the affected magneto from the engine and disassemble and inspect the affected magneto in accordance with the Corrective Action, paragraphs III.B.1. through III.B.8.a., of the CSB.

(i) If, during the inspection required by paragraph (g)(2) of this AD, no white grease is detected, before further flight, inspect and replace the magneto components, as applicable, in accordance with the Corrective Action, paragraphs III.B.8.b.1 and III.B.8.b.2, of the CSB. Where the CSB specifies discarding the roller bearing, this AD instead requires removing the roller bearing from service.

(ii) Reassemble and install the magneto in accordance with the Corrective Action, paragraph III.C., of the CSB.

(h) Installation Prohibition

After the effective date of this AD, do not install onto any engine an S–1200 series magneto having a S/N between F21EA057 and F21KA009R, inclusive, manufactured and sold between May and November 2021; or any S–1200 series magneto authorized by Continental Aerospace Technologies, Inc. PMA Supplements 1–54, having an S/N between F21EA057 and F21KA009R, inclusive, manufactured and sold between May and November 2021, unless the magneto has first undergone corrective action and the data plate has been marked in accordance with the Corrective Action, paragraph III.C.3., of the CSB.

(i) Credit for Previous Actions

You may take credit for actions required by paragraph (g) of this AD if the actions were performed before the effective date of this AD using Continental Aerospace Technologies Critical Service Bulletin CSB673, Revision B, dated April 20, 2022; Continental Ignition Systems Service Bulletin (SB) SB673, Revision A, dated March 8, 2022; or Continental Ignition Systems SB SB673, Original Issue, dated January 31, 2022.

(j) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199 to permit a one-time non-revenue ferry flight to a location where this AD can be accomplished. This ferry flight must be performed with only essential flight crew.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD.

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

(l) Related Information

For more information about this AD, contact Boyce Jones, Aviation Safety Engineer, Atlanta ACO, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5535; email: *boyce.jones@faa.gov*.

(m) Material Incorporated by Reference

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

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

(i) Continental Aerospace Technologies Critical Service Bulletin CSB673, Revision C, dated May 24, 2022.

(ii) [Reserved]

(3) For service information identified in this AD, contact Continental Aerospace Technologies, P.O. Box 90, Mobile, AL 36615; phone: (251) 436–8299; website: *www.continental.aero*.

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

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

Issued on July 25, 2022.

Christina Underwood,

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

[FR Doc. 2022–16371 Filed 7–27–22; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No. FAA–2022–1029; Amdt. No. 93–103]

RIN 2120–AL77

Extension of the Requirement for Helicopters To Use the New York North Shore Helicopter Route

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

ACTION: Interim final rule with request for comment.

SUMMARY: This interim final rule with request for comment amends the expiration date of the rule requiring pilots operating civil helicopters under Visual Flight Rules to use the New York North Shore Helicopter Route when operating along the northern shoreline of Long Island, New York. The current rule expires on August 5, 2022. The FAA finds it necessary to extend the rule for four years.

DATES: Effective July 29 2022 through July 29, 2026.

Send comments on or before August 29, 2022.

ADDRESSES: Send comments identified by docket number FAA–2022–1029 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments,

without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *https://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brian Konie, Airspace Rules and Regulations Team AJV–P21, Mission Support Services, Air Traffic Organization, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–0745; email *9-NATL-NY-NorthShore@faa.gov.*

SUPPLEMENTARY INFORMATION:

Good Cause for Immediate Adoption

Title 5 U.S.C. 553(b)(B) authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Additionally, 5 U.S.C. 553(d) generally requires that the publication or service of a substantive rule shall be made not less than 30 days before its effective date, but section 553(d)(3) provides an exception to this general requirement when the agency finds good cause to waive the delay in the effective date.

The East Hampton Town Airport (previously the East Hampton Airport) is the airport of choice for those traveling to the Hamptons because of its location and available services at the airport, particularly fueling. Other airports in the vicinity of the Hamptons include Francis S. Gabreski Airport (KFOK), a county-owned, joint civil-military airport; Montauk Airport (KMTP), a privately owned, public use airport; and Southampton Heliport (87N). Although Gabreski Airport is 26 miles from central East Hampton, limited road capacity (one lane in each direction) and congestion during the summer months make it a less attractive destination airport. Montauk Airport has a shorter runway and does not provide aircraft services, including fueling. The Southampton Heliport consists of a single helipad with no room for parking aircraft and provides neither fueling nor other aircraft services.

On September 26, 2021, East Hampton Airport's contractual grant obligations expired.[1] The FAA received written notice on January 20, 2022, from the Town of East Hampton, New York, followed by an amended request on February 17, 2022, advising that effective May 17, 2022, the Town would close the public-use East Hampton Airport and activate a new private-use, prior permission required, airport at the same location on May 19, 2022.[2] The FAA published the notice of closure of the public-use of East Hampton Airport in the **Federal Register** on April 15, 2022 (87 FR 22617). Subsequently, the FAA began deactivating the East Hampton Airport and taking the necessary steps to activate the East Hampton Town Airport.[3] On May 19, 2022, the new private-use, prior permission required, East Hampton Town Airport was activated.[4]

Notwithstanding the FAA's actions to deactivate the public-use East Hampton Airport and activate the private-use East Hampton Town Airport, the East Hampton Town Airport has not begun operating as a private-use airport. On May 16, 2022, the New York State Supreme Court issued temporary restraining orders (TRO) prohibiting the Town from ''continuing to take any steps to effectuate the closure of the airport, the conversion of the airport to a 'private use' facility, or the operation of the airport on a 'prior permission required' basis'' in response to several lawsuits.[5] To effectuate the court's orders and in light of the FAA's inability to safely forestall several aspects of the deactivation of a public-use airport process,[6] the private-use, prior permission required, East Hampton Town Airport is currently operating as if it was a public-use airport. Additionally, on June 8, 2022, the Town indicated that it may close the airport permanently.[7]

Since the time that East Hampton Airport's contractual obligations expired in 2021, the airport's operating status has remained in flux. Because the East Hampton Airport is the airport of choice for those traveling to the Hamptons, a change in the airport's operating status could conceivably have significant effects on helicopter air travel in the New York North Shore area to the east end of Long Island. For example, if the East Hampton Airport is changed to a private-use airport or closed permanently, much of the traveling public currently using the New York North Shore Helicopter Route may need to find an alternative means of traveling to their destinations in Long Island.

[1] Grant obligations are assurances that an airport provides in exchange for receiving federal grants to improve the airport. Among the grant assurances are prohibitions on restricting access to the airport based on noise and the obligation to keep the airport open until the grant obligations expire.

[2] 87 FR 22617 (April 15, 2022). Private-use airports may be able to impose limits on operations (*e.g.,* limits on the number of operations per day or limits on the time of day that aircraft may operate) that public-use airports cannot impose without complying with the Aircraft Noise and Capacity Act of 1990 (49 U.S.C. 47521 *et seq.*) See also implementing regulations at 14 CFR part 161.

[3] Letter from Marie Kennington-Gardiner, Regional Administrator, Office of the Regional Administrator Eastern Region, Federal Aviation Administration dated May 17, 2022, to Andrew Barr, Cooley LLP, available at *http://ehamptonny.gov/786/2022-Airport-News-and-Decision-Making.*

[4] In order to deactivate (*i.e.,* close) an airport for a period of one year or more, the airport operator must file a notice with the FAA of closing 90 days prior to the intended closing date. The FAA then posts a notice in the **Federal Register** announcing the closure in some cases. In order to activate (*i.e.,* open) an airport, the potential operator must file a notice 90 days in advance of construction, allowing the FAA to conduct an airport airspace analysis to determine if the proposed airport would impact traffic patterns of neighboring airports; would impact the existing airspace structure and projected programs of the FAA; along with impacts of known obstructions within the affected area, and on file with the FAA, on the proposed airport. Public-use airports and some private-use airports are then charted on FAA-issued aeronautical charts for the area in which the airport is located. The FAA determined that the East Hampton Town Airport should be charted. The Airport was charted on the New York Area charts, the New York Area Sectional Chart, the New York Terminal Area Chart, and the New York Helicopter Chart, on May 19, 2022.

[5] See *East End Hangars, Inc.* v. *Town of East Hampton,* No. 602799/2022 (N.Y. Sup. Ct. Suffolk Cty.); *The Coalition to Keep East Hampton Airport Open, Ltd.* v. *Town of East Hampton, New York,* No. 602801/2022 (N.Y. Sup. Ct. Suffolk Cty.); and, *Blade Air Mobility, Inc.* v. *Town of East Hampton,* No. 602802/2022 (N.Y. Sup. Ct. Suffolk Cty.) available at *http://ehamptonny.gov/786/2022-Airport-News-and-Decision-Making.* Separately, on May 14, 2022, the National Business Aviation Association joined with several other stakeholders in filing legal challenges to planned closure of the East Hampton Airport in the U.S. District Court for the Eastern District of New York. *Friends of the East Hampton Airport, Inc. Analar Corporation, Associated Aircraft Group, Inc. Eleventh Street Aviation LLC, Helicopter Association International, Inc. Heliflite Shares LLC,. Liberty Helicopters, Inc. Sound Aircraft Services, Inc., and National Business Aviation Association, Inc.* v. *Town of East Hampton,* No. 15–cv–2246–JS–ARL (E.D.N.Y.).

[6] By the time the FAA received notice of the TRO on May 16, 2022, it was too late to change or cancel the new charts. As a result, the airport identifier for the public-use East Hampton Airport no longer existed on May 19, 2022, and was replaced by the identifier for the private-use East Hampton Town Airport. Pilots are not able to file flight plans to the public-use airport. The public instrument procedures for the public-use airport were decommissioned and replaced by special instrument procedures. Air Traffic Controllers had been trained on new procedures for dealing with the private-use airport; retraining the controllers in the formerly-used procedures would cause confusion, which would compromise safety.

[7] *https://www.easthamptonstar.com/government/202268/if-town-cant-change-airport-it-may-close-it.*

Those alternative means could involve the use of a different air travel route or surface transportation, which would decrease the amount of air traffic using the New York North Shore Helicopter Route. The ongoing uncertainty regarding the airport's operating status prevents the FAA and the public in assessing the effects of any changes that the East Hampton Town Airport may implement that might influence potential modifications to the New York North Shore Helicopter Route, prior to the Rule's August 5, 2022, expiration date.

Further, given that there is no available timeline for resolution of the East Hampton Town Airport's operating status and subsequent adjustments operators may make, the FAA expects a 4-year extension to provide FAA with sufficient time for such issues to resolve to evaluate any new traffic redirection and consider that evaluation in assessing the current rule.

Therefore, in light of the pending expiration date, to prevent confusion among pilots using the Route and avoid disruption of the current operating environment, the FAA finds notice and comment impractical and that good cause exists to make this interim final rule extending the expiration date of the Rule, effective in less than 30 days.

Authority

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

The FAA's authority for this rule is contained in 49 U.S.C. 40103 and 44715. Under section 40103(b)(2), the Administrator of the FAA has authority to prescribe air traffic regulations on the flight of aircraft (including regulations on safe altitudes) for, among other purposes, navigating aircraft and protecting individuals and property on the ground. In addition, section 44715(a), provides that, to relieve and protect the public health and welfare from aircraft noise, the Administrator of the FAA, has the authority to prescribe regulations to control and abate aircraft noise.

I. Background

In 2012, in response to concerns from local residents regarding noise from helicopters operating over Long Island, the FAA issued the New York North Shore Helicopter Route final rule (77 FR 39911, July 6, 2012). The FAA codified the final rule in subpart H of part 93 of title 14 of the Code of Federal Regulations (14 CFR). The rule requires pilots operating civil helicopters under Visual Flight Rules (VFR) over the north shore of Long Island, between the Visual Point Lloyd Harbor (VPLYD) waypoint and Orient Point (VPOLT), to use the North Shore Helicopter Route as published in the New York Helicopter Chart (Chart). Subpart H was promulgated to maximize use of the Route, as published per the Chart, to secure and improve upon decreased levels of noise that had been voluntarily achieved. Under subpart H, pilots are permitted to deviate from the Route and altitude requirements when necessary for safety, weather conditions, or transitioning to or from a destination or point of landing. Subpart H is based on a voluntary VFR route that was developed by the FAA, working with the Eastern Region Helicopter Council. The voluntary route originally was added to the Chart on May 8, 2008. The rule has been extended three times without substantive change.[8] It is currently in effect through August 5, 2022.

II. Discussion of Interim Final Rule

This interim final rule extends, for an additional four years, the requirement for pilots of civil helicopters operating under VFR to use the North Shore Helicopter Route when transiting along the north shore of Long Island.

In the 2020 final rule extending subpart H for two years, the FAA explained that it needed to assess route modifications identified by commenters in response to the FAA's request for comments and public meetings regarding subpart H in accordance with section 182 of the FAA Reauthorization Act of 2018[9] and whether a new or modified route should be created and incorporated into regulation. Additionally, the FAA stated that it required time to evaluate the effects of the all-water route around Orient Point resulting from the voluntary agreement by the Eastern Region Helicopter Council and the effects of any changes implemented by East Hampton Airport once it ceased to be a grant obligated airport.[10] However, prior to completing these assessments, the operating status of the East Hampton Town Airport must be resolved.

Extending the requirement for helicopters to use the North Shore Helicopter Route for a four-year period will continue to foster maximum use of the Route and avoid disruption of the current operating environment while the East Hampton Town Airport's operating status is resolved and then allow the FAA a sufficient period of time to collect and assess relevant data.

III. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), as codified in 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted

[8] *The Extension of the Expiration Date of the New York North Shore Helicopter Route,* 79 FR 35488, (June 23, 2014); *Extension of the Requirement for Helicopters to Use the New York North Shore Helicopter Route,* 81 FR 48323 (June 25, 2016); and *Extension of the Requirement for Helicopters To Use the New York North Shore Helicopter Route,* 85 FR at 47897 (August 7, 2020).

[9] Section 182 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254, October 5, 2018) directed the FAA to hold a public hearing to solicit feedback on subpart H of 14 CFR part 93, from impacted communities and to provide notice of, and an opportunity for, at least 60 days of public comment with respect to subpart H. The FAA invited responses to four questions; including, should subpart H be extended, modified, or allowed to expire in 2020. Virtually all of the comments the FAA received in response to this question suggested that subpart H should either expire or be modified. *See Request for Comments on Requirement for Helicopters To Use the New York North Shore Helicopter Route,* 83 FR 55133 (Nov. 2, 2018), *Notification of Public Meetings on Requirement for Helicopters To Use the New York North Shore Helicopter Route,* 83 FR 55134 (Nov. 2, 2018), and *Notification of Replacement Public Meeting on Requirement for Helicopters To Use the New York North Shore Helicopter Route,* 83 FR 63817 (Dec. 12, 2018).

[10] The FAA notes that operators voluntarily agreed to fly the all-water route around Orient Point, and it appears that many operators, while continuing to comply with the regulation, have ceased flying the all-water route.

for inflation with base year of 1995). The FAA also analyzes this regulation under the Paperwork Reduction Act. This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined this rule is not a significant regulatory action, as defined in section 3(f) of Executive Order 12866. As notice and comment under 5 U.S.C. 553 are not required for this interim final rule, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 regarding impacts on small entities are not required. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

This interim final rule amends the expiration date of the final rule requiring pilots operating civil helicopters under Visual Flight Rules to use the New York North Shore Helicopter Route when operating along that area of Long Island, New York. As previously discussed, the FAA finds it necessary to extend subpart H for an additional four years to preserve the current operating environment while allowing sufficient time for the FAA to conduct research to assess route modifications identified by commenters and whether a new or modified route could be created and would be appropriate for incorporation into the regulations.

The FAA determined the 2012 final rule would impose minimal costs because many of the existing operators were already complying with the final rule requirements. In addition, the FAA based the 2012 final rule on a voluntary route developed by the FAA working with the Eastern Region Helicopter Council—the FAA added the voluntary route to the New York Helicopter Chart on May 8, 2008. The 2012 final rule also permits deviations from the route for safety, weather conditions, or transitioning to or from a destination or point of landing. The FAA extended the 2012 final rule in 2014, 2016, and 2020 without any substantive change. As this interim final rule further extends the 2012 final rule requirements without change, the FAA expects it will not impose additional costs.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever an agency is required by 5 U.S.C. 553, or any other law, to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after being required by that section or any other law to publish a general notice of proposed rulemaking. The FAA found good cause to forgo prior notice and comment for this rule. As notice and comment under 5 U.S.C. 553 are not required in this situation, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 are not required.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this interim final rule and determined that subpart H will preserve the current operating environment and is not considered an unnecessary obstacle to foreign commerce.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $165 million in lieu of $100 million.

This interim final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

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

F. International Compatibility and Cooperation

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

G. Environmental Analysis

FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' identifies FAA actions that, in the absence of extraordinary circumstances, are categorically excluded from requiring an environmental assessment (EA) or environmental impact statement (EIS) under the National Environmental Policy Act. This rule qualifies for the categorical exclusion in paragraph 5–6.6.f of that Order, which includes ''[r]egulations . . . excluding those that if implemented may cause a significant impact on the human environment.'' There are no extraordinary circumstances that warrant preparation of an EA or EIS.

IV. Executive Order Determinations

A. Executive Order 13132, Federalism

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

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this interim final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The agency has determined that it is not a ''significant energy action'' under the Executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

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

V. How To Obtain Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The Agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting this interim final rule. The most helpful comments reference a specific portion of the rule, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking. Before acting on this interim final rule, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The Agency may change this interim final rule in light of the comments it receives.

B. Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this interim final rule contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this interim final rule, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this rule. Submissions containing CBI should be sent to the person in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

C. Electronic Access and Filing

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

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

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

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA, visit *https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 93

Air traffic control, Airspace, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of Title 14 of the Code of Federal Regulations as follows:

PART 93—SPECIAL AIR TRAFFIC RULES

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44715, 44719, 46301.

■ 2. Revise § 93.101 to read as follows:

§ 93.101 Applicability.

This subpart prescribes a special air traffic rule for civil helicopters operating VFR along the North Shore, Long Island, New York, between July 29, 2022, and July 29, 2026.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on

Billy Nolen,

Acting Administrator.

[FR Doc. 2022–16372 Filed 7–27–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 4

[CBP Dec. 22–14]

RIN 1651–AB41

Vessel Repair Duties for Vessels Entering U.S. Ports

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: This rule amends U.S. Customs and Border Protection (CBP) regulations to streamline the vessel repair entry process by extending the timeframe from 90 days to 150 days for vessel owners, masters, or authorized agents (''vessel operators'') to provide completed vessel repair entries and to apply for relief from assessment of those vessel repair duties. Because CBP is extending the timeframe from 90 days to 150 days, CBP is also eliminating provisions that allow for requests for an additional 30-day extension to submit all of the relevant evidence as those extensions are no longer necessary.

DATES: This final rule is effective July 29, 2022.

FOR FURTHER INFORMATION CONTACT: W. Richmond Beevers, Chief, Cargo Security, Carriers, and Restricted Merchandise Branch, Regulations and Rulings, U.S. Customs and Border Protection, at 202–325–0084 or *wiley.r.beevers@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 466 of the Tariff Act of 1930, as amended (19 U.S.C. 1466), purchases for repairs or repairs made to certain vessels while outside the United States are subject to declaration, entry, and payment of ad valorem duty upon vessel arrival in any port of the United States. Duties owed for vessel repairs made in a foreign country apply to all vessels documented under U.S. law that engage in foreign or coasting trade, as well as those intended to be employed in such trade. 19 U.S.C. 1466(a). The statute also specifies the situations in which vessel operators may be relieved from paying such duties.[1]

Section 4.14 of title 19 of the Code of Federal Regulations (19 CFR 4.14) implements 19 U.S.C. 1466. Section 4.14(a)(1) requires vessel operators to declare, enter, and be subject to payment of duty for vessel repair purchases or repairs made to vessels while outside of the United States upon vessel arrival to the United States or Puerto Rico. The duties owed on these repairs and purchases are based on the actual foreign cost of the vessel repair or expenditure. 19 CFR 4.14(a)(1). Certain foreign vessel repair expenditures are not subject to declaration, entry, or duty at all. *See* 19 CFR 4.14(a)(2)(i)–(iii). Some expenditures may not require duty payments but must still follow declaration and entry procedures. *See* 19 CFR 4.14(a)(3), (h)(1)–(4).

Upon arrival, vessel operators must declare and enter all foreign repairs or related expenses to U.S. Customs and Border Protection (CBP) on CBP Form 226, or an electronic equivalent, to be processed by CBP's Vessel Repair Unit (VRU) in New Orleans, Louisiana (''vessel repair entry''). *See* 19 CFR 4.14(d), (e), (g). The vessel repair entry must include all foreign voyage expenditures for equipment, parts of equipment, repair parts, materials, and labor. 19 CFR 4.14(e). The regulations currently require a vessel operator to submit a completed vessel repair entry within 90 days of vessel arrival into the United States. 19 CFR 4.14(f). A completed vessel repair entry must contain evidence of the cost of each foreign repair or related expense. *Id.* The vessel operator can request additional time from the VRU to file a completed vessel repair entry. *Id.* The VRU may grant, and in practice almost always does grant, a 30-day extension period for vessel operators to submit the completed entry.[2] If additional time is needed, the Cargo Security, Carriers, and Restricted Merchandise Branch (CCR) at CBP Headquarters may grant, and in practice almost always does grant, a second extension.[3] Normally, in this instance, the CCR will grant an additional 30-day extension after the first extension. Therefore, in practice, vessel operators have a total of 150 days to submit a completed vessel repair entry supported by evidence showing the cost of each foreign repair or expense.

Before the vessel may depart from a U.S. port, the vessel operator must also submit the estimated cost of duties, or evidence of a bond, for all potential repairs or expenses declared in the vessel repair entry. 19 CFR 4.14(c). The current regulations set forth the circumstances in which the vessel operator may be relieved from assessment of these duties. Such relief is available when: (i) the expenditure is not considered to be a repair or purchase within the terms of 19 U.S.C. 1466 or as determined under judicial or administrative interpretation; (ii) foreign repairs or expenditures were the result of damage caused by inclement weather or other casualties; (iii) materials used for repair were made in the United States and installed by U.S. residents or the vessel's crew; (iv) materials were used for the purpose of providing dunnage for the packing of cargo, erection of temporary bulkheads, or in preparation for the carrying of liquid cargo; (v) for vessels that continuously remained outside the United States for two years, expenditures were made after the first six months of their absence; (vi) expenditures were made for Lighter Abroad Ship (LASH) operations; (vii) spare repair parts or materials were certified for use on a cargo vessel, if duty was previously paid under the appropriate U.S. commodity classification; and (viii) spare repair parts were necessarily installed prior to first entry into the United States, if duty was paid under the appropriate U.S. commodity classification. 19 U.S.C. 1466(a), (d), (e), (h); 19 CFR 4.14(h)(1)–(3).

Under the current regulations, the operator must apply for relief from these duties within 90 days of the vessel's arrival into the United States. 19 CFR 4.14(i). Similar to the timeline for submitting a completed vessel repair entry, the VRU may grant, and in practice almost always does grant, a 30-day filing extension, and the CCR may grant an additional filing extension for vessel operators to apply for relief from assessment of such duties.[4] The CCR almost always grants an additional 30-day extension, which results in an additional 60 days for vessel operators to file for relief from duty payment after the initial 90-day timeline expires. Therefore, in practice, current procedures almost always allow vessel operators a total of 150 days to file for relief from assessment of vessel repair duties.

Although both the VRU and CCR rarely deny filing extensions for vessel operators seeking to submit completed vessel repair entries or to apply for relief from assessment of vessel repair duties, the two offices are still faced with the administrative burden of processing extension requests. For instance, on average, the CCR processes 42 vessel repair extension requests annually. The VRU processes annually over three times this number of extension requests.[5] The hours expended on extension requests create an unnecessary burden on both CBP and vessel operators filing such requests with no benefit to CBP, vessel operators or the public by maintaining the extensions.[6]

[1] Vessel operators may be relieved from paying duties for foreign repairs to vessels when: materials purchased and repairs made to vessels outside the United States were a result of damage caused by inclement weather or other casualties; purchased materials were made in the United States and installed by U.S. residents or the vessel's crew; or purchased materials were used for dunnage cargo, packing, erection of temporary bulkheads, or in preparation for the carrying of liquid cargo. 19 U.S.C. 1466(d).

[2] Based on communication with the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022. A subject matter expert stated that the VRU nearly always approves the 30-day extension requests subject to timeliness of such request. In 2021–2022, VRU approved 100% of all requests for extensions.

[3] Based on communication with the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022. A subject matter expert stated that vessel operators are sophisticated users understanding what is required and as a result, CCR nearly always approves a second extension request subject to the timeliness of the request. In 2021–2022, CCR approved 100% of all second requests for extensions.

[4] *See* 19 CFR 4.14(f) for extension procedures.

[5] The VRU processes on average 152 extension requests annually. *See* Part IV, Table 1. Time Burden to Complete Extension Requests.

[6] Based on communication with the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022, subject matter experts stated that the only reason VRU or CCR had ever denied a request for an extension was an untimely request which occurred one time with VRU over the last several years. Vessel operators are sophisticated

Continued

II. Discussion of Regulatory Changes

CBP is streamlining the vessel repair entry process under 19 CFR 4.14 by amending the timeframe to submit complete vessel repair entries with supporting evidence for the costs of each repair and to apply for relief from assessment of vessel repair duties. This rule will also eliminate the need for filing extension requests. In particular, paragraphs (f) and (i) are amended to eliminate provisions allowing for extensions and to change the timeline for document submission from 90 to 150 days. These amendments allow the same timeframe as the current practice, which provides for a 90-day deadline and the potential to file two extensions, for a total of 150 days. Accordingly, the amendments will simplify the process and alleviate unnecessary burdens placed on CBP to process extension requests and on vessel operators to file such requests. The amendments are described below.

A. Evidence for Cost of Repair

Paragraph (f) requires vessel operators to submit to CBP completed vessel repair entries with supporting evidence of the final cost of each foreign repair or expenditure within 90 days of the vessel's arrival. 19 CFR 4.14(f). The vessel operator is permitted to submit initial or interim cost estimates if sufficient evidence to show final costs or expenditures is not yet available, but must submit a completed entry within 90 days of the vessel's arrival. 19 CFR 4.14(f). If additional time is needed to submit completed vessel repair entries, vessel operators are required to submit to the VRU a written request explaining their need for filing extensions before the 90-day timeline expires. 19 CFR 4.14(f). Paragraph (f) allows the VRU to grant a 30-day extension and the CCR to grant a second extension. 19 CFR 4.14(f). Current practice allows vessel operators a total of 150 days to submit vessel repair entries because both the VRU and CCR rarely deny extension requests. In practice, the CCR will grant a second 30-day extension. Therefore, the filing extensions provide vessel operators with an additional 60 days to file completed vessel repair entries. The amendment to paragraph (f) thus removes the provision regarding extensions and provides 150 days from vessel arrival for operators to submit a completed vessel repair entry, as opposed to the existing 90-day deadline and the possibility of filing for two extensions.

users who understand what is required to obtain an extension.

B. Application for Relief From Assessment of Vessel Repair Duties

Paragraph (i) requires vessel operators to apply for relief from assessment of vessel repair duties within 90 days of vessel arrival for the opportunity to qualify for relief from assessment of these duties. 19 CFR 4.14(i). An Application for Relief must clearly state the legal basis for granting relief for one of the reasons specified in paragraph (h). Although the Application for Relief is not required to be submitted in any particular format, it must certify that all repair operations performed aboard the vessel during the one-year period prior to the current submission have been declared and entered and must be supported by certain evidence outlined in paragraph (i)(1)(i)–(vi) and (i)(2).[7] 19 CFR 4.14(i)(1). Paragraph (i) allows the VRU to grant a 30-day extension and the CCR to grant a second extension for vessel operators to file for relief from assessment of vessel repair duties. Similar to the procedure for vessel repair entries in paragraph (f), the CCR normally grants a second 30-day extension. Therefore, current practice allows vessel owners 150 days to file an Application for Relief from assessment of vessel repair duties, because, as a practical matter, the VRU and CCR usually grant all extension requests. The amendments therefore remove the extension provisions and expand the original 90-day timeline to 150 days from vessel arrival for owners to apply for relief from assessment of vessel repair duties.

IV. Statutory and Regulatory Analysis

A. Inapplicability of Prior Notice and Delayed Effective Date

According to section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), rulemaking generally requires prior notice and comment and a 30-day delayed effective date, subject to specified exceptions. Pursuant to 5 U.S.C. 553(b)(3)(A), the prior notice and comment and delayed effective date requirements do not apply when agencies promulgate rules concerning agency organization, procedure, or practice. In addition, section 553(d) of the APA requires that a final rule have a 30-day delayed effective date. The APA, however, provides exceptions from the prior notice and public comment requirement and the delayed effective date requirements, when an agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest.

This rule does not require prior notice and comment because it relates to agency organization, procedure, or practice. Specifically, the final rule merely updates the regulations to simplify CBP's procedures and does not substantially change any parties' right to file evidence for the cost of vessel repair or to apply for relief from assessment of vessel repair duties. Moreover, the new amendment seeks to codify what is done in practice.

Current practice almost always provides vessel operators with 150 days to file the supporting evidence for repairs and to apply for relief from assessment of duties, which the new amendment will still allow. Current regulations allow 90 days from vessel arrival to file these documents. Upon the request of a vessel operator, the VRU and CCR usually grant two 30-day filing extensions, for a total of an additional 60 days. The final rule will eliminate the extension request procedure and allow for a total of 150 days without extensions, rather than an initial 90 days with two 30-day extensions, to file these documents. As a result, this rule merely streamlines the vessel repair entry process by eliminating the need for vessel owners to file extension requests and by providing the same timeframe for these documents to be filed.

Additionally, CBP finds that prior notice and comment are unnecessary and that good cause exists to issue this rule effective upon publication. Prior notice and comment are unnecessary because the rule does not substantively alter the underlying rights or interests of vessel operators and streamlines the process for both vessel operators and CBP.

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

[7] Each Application for Relief must include copies of: (i) itemized bills, receipts, and invoices for items shown in 19 CFR 4.14(e); (ii) photocopies of relevant parts of vessel logs, as well as of any classification society reports which detail damage and remedies; (iii) a certification by the senior officer with personal knowledge of all relevant circumstances relating to casualty damage; (iv) a certification by the senior officer with personal knowledge of all relevant circumstances relating to foreign repair expenditures; (v) a certification by the master that casualty-related expenditures were necessary to ensure the safety and seaworthiness of the vessel in reaching its U.S. port of destination; and (vi) any permits or other documents filed with or issued by any U.S. Government agency other than CBP regarding the operation of the vessel that are relevant to the request for relief. 19 CFR 4.14(i).

effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This amendment is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this regulation. In summary, CBP expects there to be a combined total savings of approximately $55,209 annually to the Federal Government and vessel owners as a result of this rule. Following is analysis of this estimated cost savings.

Purchases for repairs or repairs made to certain vessels while outside the United States are subject to entry and payment of duty. This amendment to 19 CFR 4.14 extends the timeframe for U.S. vessel operators to provide a completed vessel repair entry to CBP and to apply for relief from the assessment of duty usually required for vessel repairs occurring in a foreign country to reflect current CBP practice. Currently, vessel operators have 90 days to submit a completed vessel repair entry with supporting evidence for each repair. In certain circumstances, vessel operators can apply for relief from assessment of these duty amounts, if they provide the appropriate documentation. Vessel operators are likewise given 90 days from vessel arrival into the United States to apply for relief.

In both scenarios, current regulations, 19 CFR 4.14(f), (i), allow vessel operators to request extensions to complete vessel repair entries and apply for relief from duty assessment. Vessel operators can request two separate extensions, allowing them, in practice, a total of 150 days to provide all the necessary information to complete their vessel repair entries or Applications for Relief. This amendment to 19 CFR 4.14 changes the deadline from 90 to 150 days and eliminates the requirement that vessel operators request extensions. This amendment would obviate the need for vessel operators to make extension requests and would eliminate all costs associated with these requests. CBP estimates that this amendment would provide an overall savings to the U.S. economy by taking away the time burden associated with the extension requests for both vessel repair entries and relief from duty payments on vessel repairs made abroad.

Under the current regulations located at 19 CFR 4.14, when certain vessels undergo repairs outside of the United States, the value of the foreign repairs may be subject to duties when these vessels re-enter the United States or Puerto Rico.[8] Upon re-entry to a U.S. or Puerto Rico port, vessel operators are required to submit a vessel repair declaration and entry documentation, including an estimated duty payment (or produce evidence of a bond), before the vessel can be released from that U.S. port of entry. Specifically, the values of foreign parts and foreign repairs made to certain vessels at foreign shipyards are subject to duty upon re-entry to a U.S. or Puerto Rico port. The duty amount is based on the actual foreign costs to the vessel operator for purchases of articles used in repairs and labor costs for repairs made outside the United States by foreign shipyards and foreign labor. According to existing regulations, for articles previously imported into the United States and then exported for use in foreign vessel repairs, vessel owners are required to pay duties. The duties owed are based on the foreign purchase price of the articles when initially imported into the United States.

Vessel operators submitting vessel repair entries must provide supporting documentation validating the costs of all foreign parts and repairs. If vessel operators do not have all of the required information at the time of entry, they can file an incomplete vessel repair entry as long as they can provide complete evidence to the VRU within 90 days of vessel arrival. Vessel operators must provide the final foreign cost of articles used and any repairs within this 90-day deadline to complete a vessel repair entry. However, vessel operators may be granted an extension to complete a vessel repair entry if they are unable to before the deadline. Upon the vessel operator's submission of a written request justifying the need for additional time, the VRU may grant a 30-day extension. As discussed above, in practice, the VRU nearly always approves requests made by vessel operators for a 30-day extension.[9] A second extension may also be granted beyond the initial 30-day extension. This second request must be approved by the CCR.[10] If both requests for extensions are granted, vessel operators, in practice, are given a total of 150 days to provide complete evidence of costs for vessel repair entries. If all cost evidence is not provided by the specified deadlines, the VRU can refer the matter to U.S. Immigration and Customs Enforcement to acquire the information needed to complete the vessel repair entry.

In the current regulations, there are limited circumstances under which vessel operators can be granted relief from paying the duties on foreign articles and foreign repairs.[11] In these cases, vessel operators may apply for relief from assessment of the duties. However, Applications for Relief from assessment of vessel repair duties require a significant amount of documentation to support such claims for relief.[12] These applications must provide information regarding all vessel repair operations performed aboard that vessel within the 12-month period prior to the most current vessel repair entry. As with filing incomplete vessel repair entries, vessel operators likewise have 90 days from vessel arrival at a U.S. port to file these Applications for Relief. Vessel operators can similarly request an extension to the initial 90-day deadline to apply for relief, assuming vessel operators can justify the need for a 30-day extension. These extension requests are comparable to the extension requests for completing vessel repair entries which include: waiting on

[8] According to 19 CFR 4.14(a), duties owed for vessel repairs occurring outside the United States apply to all vessels documented under U.S. law that engage in foreign or coasting trade, as well as those intended to engage in those trades, under CBP interpretations.

[9] Based on communication with the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022. A subject matter expert stated that the VRU nearly always approves the 30-day extension requests, only 1 request had been denied in the past several years and denial was based on a late submission well after the deadline.

[10] CBP notes that these second extension requests for vessel repair entries are rarely denied. Data received from the Cargo Security, Carriers, and Restricted Merchandise Branch on October 28, 2020. A subject matter expert stated that the CCR nearly always approves a second extension request.

[11] According to 19 CFR 4.14(h) and (i), there are a few circumstances where vessels can qualify for duty relief. These include but are not limited to: matters involving vessels normally subject to 19 U.S.C. 1466(a), (d), (e), or (h). These situations include vessels that continuously remain outside the United States for two years or longer; expenditures on LASH barges; relief on certain spare repair parts or materials; and relief on certain spare parts necessarily installed on a vessel prior to their first entry into the United States.

[12] According to 19 CFR 4.14(i), each Application for Relief should include the following documentation: itemized bills, receipts, and invoices for items shown in 19 CFR 4.14(e); the cost of items for which a request for relief is made must be segregated from the cost of the other items listed in the vessel repair entry; photocopies of relevant parts of vessel logs, as well as of any classification society reports which detail damage and remedies; a certification by the senior officer with personal knowledge of all relevant circumstances relating to casualty damage (time, place, cause, and nature of damage); a certification by the senior officer with personal knowledge of all relevant circumstances relating to foreign repair expenditures (time, place, and nature of purchases and work performed); a certification by the master that casualty-related expenditures were necessary to ensure the safety and seaworthiness of the vessel in reaching its U.S. port of destination and any permits or other documents filed with or issued by any U.S. Government agency other than CBP regarding the operation of the vessel that are relevant to the request for relief.

receipts, invoices, documents, certifications, surveyor reports, and third party organization reports. The VRU determines whether to grant extensions for submitting Applications for Relief, and in practice, the VRU rarely declines such requests.[13] In addition, vessel operators can request a second extension, which the CCR may grant.[14] If the vessel operator does not file an Application for Relief or does not provide an appropriate justification for relief, the vessel operator is responsible for the full duty amount as determined by the vessel repair entry.

This amendment changes the deadline for vessel operators to provide complete information for vessel repair entries and to submit Applications for Relief. The amendment extends the time period from 90 days to 150 days and eliminates the need for extension requests. CBP believes that extending the initial deadline will provide vessel operators additional time to provide the appropriate and accurate information. In addition, by changing the deadline to 150 days, the amendment would eliminate the necessity for vessel operators to request deadline extensions to complete vessel repair entries and Applications for Relief. CBP expects that the amendment will generate savings to both vessel operators and the Federal Government by eliminating the costs associated with completing and reviewing extension requests beyond the initial 90-day deadline in the existing regulations. CBP does not expect this amendment to impose any costs to vessel operators or the Federal Government.

TABLE 1—TIME BURDEN TO COMPLETE EXTENSION REQUESTS

	Expected annual extension requests	Time burden per request to vessel operators (hours)	Annual time burden to vessel operators (hours)	Time burden per request to CBP (hours)	Annual time burden to CBP (hours)
VRU Extension Requests	152	1	152	0.5	76
CCR Extension Requests	42	1	42	0.56	24

Vessel operators and CBP will benefit from this amendment because the extension request process is time-consuming for both the government and private parties. CBP estimates that the VRU reviews approximately 152 extension requests annually, while the CCR reviews on average 42 extension requests each year.[15] CBP estimates the average time burden placed on vessel operators or representatives to complete a single extension request (both the initial and subsequent requests) is approximately one hour each.[16] Meanwhile, CBP estimates that the time burden placed on CBP to review and approve the extension requests is approximately 30 minutes (0.5 hours) to review each VRU extension request and approximately 34 minutes (0.56 hours) to review each CCR extension request.[17]

Benefits From Eliminating VRU Extension Requests

Extension requests for vessel repair entries and applications for duty assessment relief are typically filed on behalf of the vessel operators by legal representatives or vessel agents. Unfortunately, CBP does not have exact data on the proportion of how many extension requests are completed by legal representatives on behalf of the vessel operators and how many are filed by vessel agents. Therefore, CBP assumes that half of all extension requests are filed by legal representatives and half are filed by vessel agents.

TABLE 2—EXPECTED ANNUAL SAVINGS FROM ELIMINATING VRU 30-DAY EXTENSION REQUESTS

	Estimated time burden to vessel operators (hours)	Estimated time burden to vessel legal representatives (hours)	Cost to vessel agents	Cost to vessel legal representatives	Estimated time burden to CBP (hours)	Cost to CBP	Total savings
VRU Extension Requests	76	76	$4,265	$32,669	76	$5,796	$42,730

On average, CBP estimates that vessel operators file approximately 152 extension requests every year that are reviewed by the VRU. CBP assumes that half of these 152 requests (76) are filed by a vessel operator's legal representative and half (76) are filed by vessel agents. The expected savings to vessel operators from eliminating these extension requests is based on the estimated burden hours for half of the VRU extension requests (76 hours, 1 hour per request), multiplied by the average loaded hourly wage rate for vessel legal representatives ($429.86). CBP determined that this is the best estimate for private lawyers hired outside of a company, because the data

[13] Based on communication with the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022; subject matter expert stated that the VRU essentially always approves the 30-day extension requests. During the past several years, only 1 request has been denied and the denial was solely due to the extension request being submitted well after the deadline.

[14] CBP notes that these second extension requests for Applications for Relief are rarely denied. Data received from the Cargo Security, Carriers, and Restricted Merchandise Branch on April 13, 2022; subject matter expert stated that the CCR nearly always approves a second extension request.

[15] Data provided by the Cargo Security, Carriers, and Restricted Merchandise Branch on November 9, 2020. Data obtained included the average number of extension requests reviewed by the VRU and CCR from FY 2018–FY 2020. CBP calculated the average annual expected extension requests by looking at the annual requests reviewed in FY 2018, FY 2019 and FY 2020. The extension request numbers include both extension requests for completing vessel repair entries and applications for duty assessment relief.

[16] Data received from the Vessel Repair Unit on November 10, 2020. Subject matter expert's best estimate on time burden placed on vessel operators to file extension requests is approximately one hour.

[17] Data obtained from the Cargo Security, Carriers, and Restricted Merchandise Branch on October 28, 2020, providing an estimated time burden on CBP to review each VRU and each CCR extension request.

was obtained from an American Intellectual Property Law Association (AIPLA) study on the average hourly billing rate for lawyers. AIPLA's study surveyed intellectual property (IP) lawyers and was used in the 2017 Report of the Economic Survey. The study found the median hourly billing rate for these lawyers was $400 in 2016 dollars, which is the most recent data available, and $429.86 after adjustment to 2020 dollars.[18] To estimate the cost of filing VRU extension requests imposed on vessel agents, CBP used the estimated burden hours for half of VRU extension requests (76 hours, 1 hour per request), multiplied by the average loaded hourly wage rate for vessel operators ($56.12).[19] CBP estimated that the savings each year from eliminating these extension requests to vessel agents ($4,265) and legal representatives ($32,669) would be approximately $36,934.

In addition to the cost to vessel operators, the Federal Government incurs costs from reviewing VRU extension requests every year. The expected annual cost to the Federal Government associated with the review of VRU extension requests is based on the number of responses that must be reviewed (152) multiplied by the time burden to review and process each response (0.5 hours) = 76 hours. This is then multiplied by the average hourly loaded rate for other CBP employees ($76.26) = $5,796.[20] CBP thus estimates that the savings to the Federal Government from eliminating VRU requests would be approximately $5,796 on an annual basis. Considering the combined savings to vessel operators and the Federal Government as a result of eliminating VRU extension requests, CBP estimates that this rule's annual savings is approximately $42,730.

Benefits From Eliminating CCR Extension Requests

As discussed above, CBP expects that, on average, the CCR reviews about 42 requests for 30-day extensions every year. These amendments will have the effect of eliminating extension requests and their associated costs, constituting a net savings to all associated parties. CBP calculated these costs by combining the costs to vessel operators and the Federal Government for filing and reviewing these subsequent extension requests, for completing vessel repair entries, and for applying for relief from duty payments. CBP assumes that the time burden on vessel operators to file the subsequent extension requests (which are reviewed by the CCR) is one hour per extension request. Like extension requests to the VRU, CBP expects that the costs incurred by these extension requests to the CCR represent potential savings from the amendment. CBP expects that half of the 42 extension requests to the CCR (21) are completed by legal representatives on behalf of vessel operators and half (21) are completed by vessel agents.

TABLE 3—EXPECTED ANNUAL SAVINGS FROM ELIMINATING CCR 30-DAY EXTENSION REQUESTS

	Estimated time burden to vessel operators (hours)	Estimated time burden to vessel legal representatives (hours)	Cost to vessel agents	Cost to vessel legal representatives	Estimated time burden to CBP (hours)	Cost to CBP	Total savings
CCR Extension Requests	21	21	$1,169	$8,955	24	$2,354	$12,479

CBP calculated the savings from removing the subsequent requests for 30-day extensions based on the estimated burden hours for half of the CCR extension requests (21 hours, 1 hour per request), multiplied by the average loaded hourly wage rate for vessel legal representatives equaling $429.86).[21] For the second half of the CCR extension requests, which CBP assumes are filed by vessel agents, CBP used the estimated burden hours for half of the CCR extension requests (21 hours, 1 hour per request), multiplied by the average loaded hourly wage rate for vessel operators equaling $56.12.[22] CBP calculated that the estimated annual savings to vessel operators by eliminating the CCR extension requests will be approximately $10,125.

By eliminating the need for subsequent extension requests, the amendments will provide savings to the Federal Government, as the CCR staff would no longer need to review extension requests. The estimated annual savings from this portion of the

[18] American Intellectual Property Law Association. *2017 Report of the Economic Survey.* ''Billable Hours, Billing Rate, Dollars Billed (Q29, Q30, Q27).'' June 2017. CBP calculated the 2020 adjusted dollar amount using the percent increase in the Annual Average GDP Price Deflator (2015 = 100) between 2016 and 2020. The annual average GDP Price Deflator value in 2016 = 101.0481, the annual average GDP Price Deflator value in 2020 = 108.5904, the percent increase was estimated to be around 7.4641% (108.5904/101.0481 = 1.07.4641 or 7.4641%). This percent increase was applied to the 2016 estimated hourly billing rate of $400 for external attorneys to estimate the 2020 hourly billing rate of $429.86 for external attorneys.

[19] CBP calculated this loaded wage rate by first multiplying the Bureau of Labor Statistics' (BLS) 2020 median hourly wage rate for Captains, Mates, and Pilots of Water Vessels ($37.08) by the ratio of BLS' average 2020 total compensation to wages and salaries for Transportation and Material Moving occupations (1.5134), the assumed occupational group for captains, mates, and pilots of water vessels, to account for non-salary employee benefits. These figures are in 2020 U.S. dollars and CBP assumes an annual growth rate of 0 percent; the 2020 U.S. dollar values are equal to the 2021 U.S. dollar values.

[20] Data obtained from the Cargo Security, Carriers, and Restricted Merchandise Branch on October 28, 2020. The Cargo Security, Carriers, and Restricted Merchandise Branch calculated the time burden to GS–12 litigation specialists at 30 minutes to review each VRU extension requests. CBP used its estimates for Other CBP Employees at the GS–12 Step 3 level, as the best proxy for average hourly loaded wage rate. CBP based this wage on the FY 2021 salary and benefits of the national average of other CBP positions, which is equal to a GS–12, Step 3. Source: Email correspondence with CBP's Office of Finance on September 7, 2021.

[21] CBP determined this is the best estimate for private lawyers hired outside of a company and was obtained from an American Intellectual Property Law Association (AIPLA) study on the average hourly billing rate for lawyers. AIPLA's study surveyed intellectual property (IP) lawyers that were used in the *2017 Report of the Economic Survey.* The median hourly billing rate for these lawyers was $400 in 2016 dollars, which is the most recent data available, and $424.75 after adjustment to 2019 dollars. American Intellectual Property Law Association. *2017 Report of the Economic Survey.* ''Billable Hours, Billing Rate, Dollars Billed (Q29, Q30, Q27).'' June 2017. CBP calculated the 2020 adjusted dollar amount using the percent increase in the Annual Average GDP Price Deflator (2015 = 100) between 2016 and 2020. The annual average GDP Price Deflator value in 2016 = 101.0481, the annual average GDP Price Deflator value in 2020 = 108.5904, the percent increase was estimated to be around 7.4641% (108.5904/101.0481 = 1.074641 or 7.4641%). This percent increase was applied to the 2016 estimated hourly billing rate of $400 for external attorneys to estimate the 2020 hourly billing rate of $429.86 for external attorneys.

[22] CBP calculated this loaded wage rate by first multiplying the Bureau of Labor Statistics' (BLS) 2020 median hourly wage rate for Captains, Mates, and Pilots of Water Vessels ($37.08) by the ratio of BLS' average 2020 total compensation to wages and salaries for Transportation and Material Moving occupations (1.5134), the assumed occupational group for captains, mates, and pilots of water vessels, to account for non-salary employee benefits. These figures are in 2020 U.S. dollars and CBP assumes an annual growth rate of 0 percent; the 2020 U.S. dollar values are equal to the 2021 U.S. dollar values.

amendment to the Federal Government is based on the number of responses that must be reviewed (42) multiplied by the time burden to review and process each response (0.5625 hours) = 24 hours multiplied by the average hourly loaded wage rate for a CBP attorney-advisor ($98.10) = $2,354.[23] [24] The total savings from eliminating CCR extension requests was estimated by combining savings to both vessel operators ($10,125) and CBP ($2,354), which is approximately $12,479 each year.

CBP expects the amendment will result in savings to the U.S. economy on an annual basis. CBP calculated the total savings as the combination of savings accrued by both the Federal Government and vessel operators from extending the filing deadlines to 150 days. CBP calculated the total savings by adding the expected savings to vessel operators generated by eliminating VRU extension requests ($36,934) and CCR extension requests ($10,125). CBP also included in total savings of the amendment, the added savings to the Federal Government generated by eliminating VRU extension requests ($5,796) and CCR extension requests ($2,354). CBP estimates that the overall savings to the U.S. economy from this amendment will be approximately $55,209 each year.

Overall, CBP expects that the impact from amending the deadlines from 90 to 150 days for vessel operators to provide completed vessel repair entries and applications for duty assessment relief does not result in a ''significant'' economic impact in any given year. After considering the impacts of the amendment, CBP expects there to be a net savings of approximately $55,209 annually to the U.S. economy. At the same time, CBP does not expect any costs associated with this amendment.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. As there is no collection of information in this document, the provisions of the Paperwork Reduction Act are inapplicable.

V. Signing Authority

This document is being issued in accordance with 19 CFR 0.2(a), which provides that the authority of the Secretary of the Treasury with respect to CBP regulations that are not related to customs revenue functions was transferred to the Secretary of Homeland Security pursuant to Section 403(l) of the Homeland Security Act of 2002. Accordingly, this final rule to amend such regulations may be signed by the Secretary of Homeland Security (or his or her delegate).

List of Subjects in 19 CFR Part 4

Exports, Freight, Harbors, Maritime carriers, Oil pollution, Reporting and recordkeeping requirements, Vessels.

Amendments to the Regulations

For the reasons set forth in the preamble, CBP amends part 4 of title 19 of the Code of Federal Regulations (19 CFR part 4) as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

■ 1. The general authority citation for part 4 and the specific authority citation for § 4.14 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1415, 1431, 1433, 1434, 1624, 2071 note; 46 U.S.C. 501, 60105.

* * * * *

Section 4.14 also issued under 19 U.S.C. 1466, 1498; 31 U.S.C. 9701.

* * * * *

■ 2. In § 4.14, revise paragraphs (f) and (i)(1) to read as follows:

§ 4.14 Equipment purchases for, and repairs to, American vessels.

* * * * *

(f) *Time limit for submitting evidence of cost.* A complete vessel repair entry must be supported by evidence showing the cost of each item entered. If the entry is incomplete when submitted, evidence to make it complete must be received by the VRU as identified in paragraph (g) of this section within 150 calendar days from the date of vessel arrival. That evidence must include the final cost of repairs. In the event that all final cost evidence is not furnished within 150 days, or is of doubtful authenticity, the VRU may refer the matter to U.S. Immigration and Customs Enforcement to begin procedures to obtain the needed evidence. That agency may also investigate the reason for a failure to file or for an untimely submission. Unexplained or unjustified delays in providing CBP with sufficient information to properly determine duty may result in penalty action as specified in paragraph (j) of this section.

* * * * *

(i) * * *

(1) *Applications for Relief.* Relief from the assessment of vessel repair duty will not be granted unless an Application for Relief is filed with CBP. Relief will not be granted based merely upon a claim for relief made at the time of entry under paragraph (e) of this section. If relief is sought, an Application is not required to be presented in any particular format, but it must clearly present the legal basis for granting relief, as specified in paragraph (h) of this section. An Application must also state that all repair operations performed aboard a vessel during the one-year period prior to the current submission have been declared and entered. A valid Application is required to be supported by complete evidence as detailed in paragraphs (i)(1)(i) through (vi) and (i)(2) of this section. Except as further provided in this paragraph, the deadline for receipt of an Application and supporting evidence is 150 calendar days from the date that the vessel first arrived in the United States following foreign operations. Applications must be addressed and submitted by the vessel operator to the VRU and will be decided in that unit. The VRU may seek the advice of the Cargo Security, Carriers & Restricted Merchandise Branch, Office of Trade, in CBP Headquarters with regard to any specific item or issue which has not been addressed by clear precedent. If no Application is filed or if a submission which does not meet the minimal standards of an Application for Relief is

[23] Data obtained from the Cargo Security, Carriers, and Restricted Merchandise Branch on October 28, 2020, providing an estimated time burden to the CCR to review the secondary extension requests. Of the 80 requests reviewed in FY 2020, the estimated time burden was about 45 hours for attorney-advisors, equivalent to about 0.5625 hours per request to review. A lack of detailed data for FY 2019 and FY 2018 prevented CBP from obtaining exact time burdens to complete the requests made during those years. Therefore, CBP used the FY 2020 average time burden per request and applied that average to the total number of requests reviewed in FY 2019 and FY 2018 to estimate the annual expected time burden associated with secondary extension requests.

[24] CBP based this wage on the FY 2021 salary and benefits of the national average of CBP Attorney positions. Source: Email correspondence with CBP's Office of Finance on March 18, 2022.

received, the duty amount will be determined without regard to any potential claims for relief from duty assessment (see paragraph (h) of this section). Each Application for Relief must include copies of:

* * * * *

Alejandro N. Mayorkas,

Secretary of Homeland Security.

[FR Doc. 2022–16233 Filed 7–28–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0627]

Safety Zone; Oswego Harbor Fest Fireworks

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Oswego Harbor Fest Fireworks. This safety zone is necessary for the safety of life on navigable waterways during this display. Our regulation for limited access areas within the Captain of the Port Buffalo Zone identifies the regulated area for this event in Oswego, NY. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Safety Zone Coordinator or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation listed in 33 CFR 165.939 Table 165.939 (b)(28) will be enforced from 9 p.m. through 10 p.m. on July 30, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, contact LTJG William Kelley, Chief of Waterways Management, Sector Buffalo, U.S. Coast Guard; telephone 716–843–9301, email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Oswego Harbor Fest Fireworks Safety Zone in 33 CFR 165.939 listed in the Table 165.939 (b)(28). The safety zone will be enforced on all waters of Oswego Harbor, Oswego, NY contained within a 700-foot radius of position 43°27′54.9″ N, 076°31′20.48″ W along with a 350-foot radius of the break wall between positions 43°27′86.0″ N, 076°31′44.3″ W then Northeast to 43°28′01.4″ N, 076°31′44.6″ W, from 9 p.m. through 10 p.m. on July 30, 2022.

Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port (COTP) Buffalo or his designated representative; designation need not be in writing. Those seeking permission to enter these safety zones may request permission from the COTP Buffalo via channel 16, VHF–FM. Vessels and persons granted permission to enter the safety zone shall obey the directions of the COTP Buffalo or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement periods via Broadcast Notice to Mariners or other suitable means. If the COTP Buffalo determines that the safety zone need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone. This notice is issued under the authority of 5 U.S.C. 552(a).

Dated: July 25, 2022.

M.I. Kuperman,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2022–16265 Filed 7–28–22; 8:45 am]

BILLING CODE 9110–04–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3040

[Docket No. RM2020–8]

Update to Product Lists

AGENCY: Postal Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Commission is announcing an update to the Market Dominant and Competitive product lists. This action reflects a publication policy adopted by Commission rules. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The Market Dominant and Competitive product lists, which are re-published in their entirety, include these updates.

DATES: This rule is effective September 12, 2022, without further action, unless adverse comment is received by August 29, 2022. If adverse comment is received, the Commission will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: For additional information, this document can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6800.

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Commission Process
III. Authorization
IV. Modifications
V. Ordering Paragraphs

I. Introduction

Pursuant to 39 U.S.C. 3642(d)(2) and 39 CFR 3040.103, the Commission provides a Notice of Update to Product Lists by listing all necessary modifications to both the Market Dominant and Competitive product lists between April 1, 2022 and June 30, 2022.

II. Commission Process

Pursuant to 39 CFR part 3040, the Commission maintains a Mail Classification Schedule (MCS) that includes rates, fees, and product descriptions for each Market Dominant and Competitive product, as well as product lists that categorize Postal Service products as either Market Dominant or Competitive. *See generally* 39 CFR part 3040. The product lists are published in the Code of Federal Regulations as 39 CFR Appendix A to Subpart A of Part 3040—Market Dominant Product List and Appendix B to Subpart A of Part 3040—Competitive Product List pursuant to 39 U.S.C. 3642(d)(2). *See* 39 U.S.C. 3642(d)(2). Both the MCS and its product lists are updated by the Commission on its website on a quarterly basis.[1] In addition, these quarterly updates to the product lists are also published in the **Federal Register** pursuant to 39 CFR 3040.103. *See* 39 CFR 3040.103.

III. Authorization

Pursuant to 39 CFR 3040.103(d)(1), this Notice of Update to Product Lists identifies any modifications made to the Market Dominant or Competitive product list, including product additions, removals, and transfers.[2] Pursuant to 39 CFR 3040.103(d)(2), the modifications identified in this document result from the Commission's most recent MCS update posted on the

[1] *See https://www.prc.gov/mail-classification-schedule* in the Current MCS section.

[2] 39 CFR 3040.103(d)(1). More detailed information (*e.g.,* Docket Nos., Order Nos., effective dates, and extensions) for each Market Dominant and Competitive product can be found in the MCS, including the ''Revision History'' section. *See, e.g.,* file ''*MCSRedline01092022.docx,*'' available at *https://www.prc.gov/mail-classification-schedule.*

Commission's website on June 30, 2022, and supersede all previous product lists.[3]

IV. Modifications

The following list of products is being added to 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List:

1. Parcel Select Contract 49
2. Priority Mail Contract 738
3. Priority Mail Contract 739
4. Priority Mail Contract 740
5. Priority Mail Contract 741
6. Priority Mail Contract 742
7. Priority Mail Contract 743
8. Priority Mail Contract 744
9. Priority Mail Contract 745
10. Priority Mail Contract 746
11. Priority Mail Contract 747
12. Priority Mail Contract 748
13. Priority Mail Contract 749
14. Priority Mail Contract 750
15. Priority Mail Express Contract 94
16. Priority Mail & First-Class Package Service Contract 216
17. Priority Mail & First-Class Package Service Contract 217
18. Priority Mail Express & Priority Mail Contract 131
19. Priority Mail Express & Priority Mail Contract 132
20. Priority Mail Express & Priority Mail Contract 133
21. Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 4
22. Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 5

The following list of products is being removed from 39 CFR Appendix A to Subpart A of Part 3040—Market Dominant Product List:

1. Extended Mail Forwarding
2. Commercial PO Box Redirect Service

The following list of products is being removed from 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List:

1. Parcel Return Service Contract 14
2. Priority Mail Contract 479
3. Priority Mail Contract 505
4. Priority Mail Contract 507
5. Priority Mail Contract 509
6. Priority Mail Contract 523
7. Priority Mail Contract 529
8. Priority Mail Contract 531
9. Priority Mail Contract 533
10. Priority Mail Contract 661
11. Priority Mail Contract 664
12. Priority Mail Contract 691
13. Priority Mail Contract 713
14. Priority Mail Contract 717
15. Priority Mail Contract 719
16. Priority Mail & First-Class Package Service Contract 110
17. Priority Mail & First-Class Package Service Contract 115
18. Priority Mail & First-Class Package Service Contract 185
19. Priority Mail Express Contract 74
20. Priority Mail Express & Priority Mail Contract 84
21. Priority Mail Express & Priority Mail Contract 92
22. Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 4
23. Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 5
24. Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 6
25. Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 7

The above-referenced changes to the Market Dominant product list and the Competitive product list are incorporated into 39 CFR Appendix A and B to Subpart A of Part 3040.

V. Ordering Paragraphs

It is ordered:

1. Part 3040 of title 39, Code of Federal Regulations, is amended as set forth below the signature of this Notice, effective 45 days after the date of publication of the Notice in the **Federal Register** without further action, unless adverse comments are received.

2. The Secretary shall arrange for publication of the Notice in the **Federal Register**.

3. Interested persons may submit adverse comments no later than 30 days from the date of the publication of this Notice in the **Federal Register**.

4. If adverse comments are received, the Secretary will publish a timely withdrawal of the Notice in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

List of Subjects in 39 CFR Part 3040

Administrative practice and procedure, Postal Service.

For the reasons discussed in the preamble, the Postal Regulatory Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3040—PRODUCT LISTS

■ 1. The authority citation for part 3040 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to Subpart A of Part 3040 to read as follows:

Appendix A to Subpart A of Part 3040—Market Dominant Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

FIRST-CLASS MAIL *
Single-Piece Letters/Postcards
Presorted Letters/Postcards
Flats
Outbound Single-Piece First-Class Mail International
Inbound Letter Post
USPS MARKETING MAIL (COMMERCIAL AND NONPROFIT) *
High Density and Saturation Letters
High Density and Saturation Flats/Parcels
Carrier Route
Letters
Flats
Parcels
Every Door Direct Mail—Retail
PERIODICALS *
In-County Periodicals
Outside County Periodicals
PACKAGE SERVICES *
Alaska Bypass Service
Bound Printed Matter Flats
Bound Printed Matter Parcels
Media Mail/Library Mail
SPECIAL SERVICES *
Ancillary Services
International Ancillary Services
Address Management Services
Caller Service
Credit Card Authentication
International Reply Coupon Service
International Business Reply Mail Service
Money Orders
Post Office Box Service
Stamp Fulfillment Services
NEGOTIATED SERVICE AGREEMENTS *
Domestic *
International *
Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators
NONPOSTAL SERVICES *
Alliances with the Private Sector to Defray Cost of Key Postal Functions
Philatelic Sales
MARKET TESTS *
USPS Connect Local Mail

■ 3. Revise Appendix B to Subpart A of Part 3040 to read as follows:

Appendix B to Subpart A of Part 3040—Competitive Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

DOMESTIC PRODUCTS *
Priority Mail Express
Priority Mail
Parcel Select
Parcel Return Service
First-Class Package Service

[3] Previous versions of the MCS and its product lists can be found on the Commission's website, available at *https://www.prc.gov/mail-classification-schedule* in the MCS Archives section.

USPS Retail Ground
INTERNATIONAL PRODUCTS *
Outbound International Expedited Services
Inbound Parcel Post (at UPU rates)
Outbound Priority Mail International
International Priority Airmail (IPA)
International Surface Air Lift (ISAL)
International Direct Sacks—M-Bags
Outbound Single-Piece First-Class Package International Service
Inbound Letter Post Small Packets and Bulky Letters
NEGOTIATED SERVICE AGREEMENTS *
Domestic *
Priority Mail Express Contract 77
Priority Mail Express Contract 81
Priority Mail Express Contract 83
Priority Mail Express Contract 87
Priority Mail Express Contract 88
Priority Mail Express Contract 91
Priority Mail Express Contract 92
Priority Mail Express Contract 93
Priority Mail Express Contract 94
Parcel Return Service Contract 17
Parcel Return Service Contract 18
Priority Mail Contract 80
Priority Mail Contract 153
Priority Mail Contract 292
Priority Mail Contract 360
Priority Mail Contract 504
Priority Mail Contract 511
Priority Mail Contract 530
Priority Mail Contract 535
Priority Mail Contract 542
Priority Mail Contract 543
Priority Mail Contract 544
Priority Mail Contract 547
Priority Mail Contract 550
Priority Mail Contract 551
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Priority Mail Contract 573
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Priority Mail Contract 589
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Priority Mail Contract 591
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Priority Mail Contract 596
Priority Mail Contract 601
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Priority Mail Contract 611
Priority Mail Contract 614
Priority Mail Contract 615
Priority Mail Contract 618
Priority Mail Contract 628
Priority Mail Contract 631
Priority Mail Contract 640
Priority Mail Contract 641
Priority Mail Contract 642
Priority Mail Contract 645
Priority Mail Contract 647
Priority Mail Contract 655
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Priority Mail Contract 750
Priority Mail Express & Priority Mail Contract 48
Priority Mail Express & Priority Mail Contract 90
Priority Mail Express & Priority Mail Contract 95
Priority Mail Express & Priority Mail Contract 96
Priority Mail Express & Priority Mail Contract 99
Priority Mail Express & Priority Mail Contract 102
Priority Mail Express & Priority Mail Contract 103
Priority Mail Express & Priority Mail Contract 114
Priority Mail Express & Priority Mail Contract 116
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Priority Mail Express & Priority Mail Contract 122
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Priority Mail Express & Priority Mail Contract 128
Priority Mail Express & Priority Mail Contract 129
Priority Mail Express & Priority Mail Contract 130
Priority Mail Express & Priority Mail Contract 131
Priority Mail Express & Priority Mail Contract 132
Priority Mail Express & Priority Mail Contract 133
Parcel Select & Parcel Return Service Contract 7
Parcel Select & Parcel Return Service Contract 9
Parcel Select & Parcel Return Service Contract 10
Parcel Select & Parcel Return Service Contract 11
Parcel Select & Parcel Return Service Contract 13
Parcel Select & Parcel Return Service Contract 14
Parcel Select Contract 34
Parcel Select Contract 35
Parcel Select Contract 37
Parcel Select Contract 38
Parcel Select Contract 39
Parcel Select Contract 40
Parcel Select Contract 41
Parcel Select Contract 42
Parcel Select Contract 43
Parcel Select Contract 44
Parcel Select Contract 45
Parcel Select Contract 46
Parcel Select Contract 47
Parcel Select Contract 48
Parcel Select Contract 49
Priority Mail—Non-Published Rates 1
Priority Mail—Non-Published Rates 2
First-Class Package Service Contract 87
First-Class Package Service Contract 99
First-Class Package Service Contract 100
First-Class Package Service Contract 103
First-Class Package Service Contract 104
First-Class Package Service Contract 106
First-Class Package Service Contract 107
First-Class Package Service Contract 108
First-Class Package Service Contract 109
First-Class Package Service Contract 110
First-Class Package Service Contract 112
First-Class Package Service Contract 114
First-Class Package Service Contract 115
First-Class Package Service Contract 116
First-Class Package Service Contract 117
First-Class Package Service Contract 118
First-Class Package Service Contract 119
Priority Mail Express, Priority Mail & First-Class Package Service Contract 51
Priority Mail Express, Priority Mail & First-Class Package Service Contract 53

Priority Mail Express, Priority Mail & First-Class Package Service Contract 55
Priority Mail Express, Priority Mail & First-Class Package Service Contract 57
Priority Mail Express, Priority Mail & First-Class Package Service Contract 58
Priority Mail Express, Priority Mail & First-Class Package Service Contract 62
Priority Mail Express, Priority Mail & First-Class Package Service Contract 63
Priority Mail Express, Priority Mail & First-Class Package Service Contract 66
Priority Mail Express, Priority Mail & First-Class Package Service Contract 67
Priority Mail Express, Priority Mail & First-Class Package Service Contract 69
Priority Mail Express, Priority Mail & First-Class Package Service Contract 71
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Priority Mail Express, Priority Mail & First-Class Package Service Contract 75
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Priority Mail Express, Priority Mail & First-Class Package Service Contract 77
Priority Mail Express, Priority Mail & First-Class Package Service Contract 78
Priority Mail & First-Class Package Service Contract 9
Priority Mail & First-Class Package Service Contract 26
Priority Mail & First-Class Package Service Contract 95
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Priority Mail & First-Class Package Service Contract 213
Priority Mail & First-Class Package Service Contract 214
Priority Mail & First-Class Package Service Contract 215
Priority Mail & First-Class Package Service Contract 216
Priority Mail & First-Class Package Service Contract 217
Priority Mail & Parcel Select Contract 4
Priority Mail & Parcel Select Contract 5
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 1
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 2
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 3
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 5
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 6
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 7
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 8
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 9
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 10
Priority Mail, First-Class Package Service & Parcel Select Contract 1
Priority Mail, First-Class Package Service & Parcel Select Contract 2
Priority Mail, First-Class Package Service & Parcel Select Contract 3
Outbound International *
Global Expedited Package Services (GEPS) Contracts
- GEPS 3
- GEPS 5
- GEPS 6
- GEPS 7
- GEPS 8
- GEPS 9
- GEPS 10

Global Bulk Economy (GBE) Contracts
Global Plus Contracts
- Global Plus 1C
- Global Plus 1D
- Global Plus 1E
- Global Plus 2C
- Global Plus 3
- Global Plus 4
- Global Plus 5
- Global Plus 6

Global Reseller Expedited Package Contracts
- Global Reseller Expedited Package Services 1
- Global Reseller Expedited Package Services 2

Global Reseller Expedited Package Services 3
Global Reseller Expedited Package Services 4
Global Expedited Package Services (GEPS)—Non-Published Rates
Global Expedited Package Services (GEPS)—Non-Published Rates 2
Global Expedited Package Services (GEPS)—Non-Published Rates 3
Global Expedited Package Services (GEPS)—Non-Published Rates 4
Global Expedited Package Services (GEPS)—Non-Published Rates 5
Global Expedited Package Services (GEPS)—Non-Published Rates 6
Global Expedited Package Services (GEPS)—Non-Published Rates 7
Global Expedited Package Services (GEPS)—Non-Published Rates 8
Global Expedited Package Services (GEPS)—Non-Published Rates 9
Global Expedited Package Services (GEPS)—Non-Published Rates 10
Global Expedited Package Services (GEPS)—Non-Published Rates 11
Global Expedited Package Services (GEPS)—Non-Published Rates 12
Global Expedited Package Services (GEPS)—Non-Published Rates 13
Global Expedited Package Services (GEPS)—Non-Published Rates 14
Global Expedited Package Services (GEPS)—Non-Published Rates 15
Priority Mail International Regional Rate Boxes—Non-Published Rates
Outbound Competitive International Merchandise Return Service Agreement with Royal Mail Group, Ltd.
Priority Mail International Regional Rate Boxes Contracts
Priority Mail International Regional Rate Boxes Contracts 1
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 1
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 2
Alternative Delivery Provider (ADP) Contracts
ADP 1
Alternative Delivery Provider Reseller (ADPR) Contracts
ADPR 1
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contracts
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 4
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 5
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contracts
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 2
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 8
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 10
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Greeting Cards, Gift Cards, and Stationery
International Ancillary Services
International Money Transfer Service—Outbound
International Money Transfer Service—Inbound
Premium Forwarding Service
Shipping and Mailing Supplies
Post Office Box Service
Competitive Ancillary Services

NONPOSTAL SERVICES *
Advertising
Licensing of Intellectual Property other than Officially Licensed Retail Products (OLRP)
Mail Service Promotion
Officially Licensed Retail Products (OLRP)
Passport Photo Service
Photocopying Service
Rental, Leasing, Licensing or other Non-Sale Disposition of Tangible Property
Training Facilities and Related Services
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[FR Doc. 2022–15974 Filed 7–28–22; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2020–0437; FRL–8698–02–R6]

Air Plan Approval; Oklahoma; Volatile Organic Compound Emissions in Nonattainment Areas and Former Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving revisions to the State Implementation Plan (SIP) for Oklahoma submitted by the State of Oklahoma designee with a letter dated May 7, 2020. The submittal covers updates to the Oklahoma SIP, as contained in the State's 2019 annual SIP update. Specifically, this action addresses revisions to Oklahoma Administrative Code (OAC) Title 252 Chapter 100 Subchapter 39, Emission of Volatile Organic Compounds (VOCs) in Nonattainment Areas and Former Nonattainment Areas. There are two Oklahoma counties affected by this action: Tulsa County and Oklahoma County.

DATES: This rule is effective on August 29, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2020–0437. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Clovis Steib, EPA Region 6 Office, Infrastructure and Ozone Section, 214–665–7566, *steib.clovis@epa.gov.* Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office may be closed to the public to reduce the risk of transmitting COVID–19. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

The background for this action is discussed in detail in our July 22, 2021, proposal (86 FR 38627). In that document we proposed to approve revisions to the SIP for Oklahoma submitted by the State of Oklahoma with a letter dated May 7, 2020. Specifically, the action addressed revisions to OAC Title 252 Chapter 100 Subchapter 39, Sections 4, 16, 40, and 41. The revisions corrected errors and made these sections of the Oklahoma SIP consistent with EPA's rules. The two areas in Oklahoma affected by this action are Tulsa County and Oklahoma County.

We received comments on our proposal from one commenter. Our response to the comments follows.

II. Response to Comments

Comment: One commenter stated that it is important for citizens to stay informed and be kept up to date on Federal government revisions and regulations, such as this proposed approval action on the Oklahoma SIP.

Response: Public comment is just one part of an extensive rulemaking process. It is an invaluable gateway to plug in to the regulatory process because it is required of all agencies, across statutes, for any new regulation. Under the Administrative Procedures Act (1946), Federal agencies like the EPA, are required to request comments on new regulation proposals by all members of the public. We thank the commenter for their interest and taking the time to submit their response; as well as encouraging their fellow citizens to engage in the public comment process. No changes to the proposal were made in response to the comment.

III. Impact on Areas of Indian Country

As stated in the proposed action, following the U.S. Supreme Court decision in *McGirt* v. *Oklahoma*, 140 S.Ct. 2452 (2020), the Governor of the State of Oklahoma requested approval under Section 10211(a) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act of 2005: A Legacy for Users, Public Law 109–59, 119 Stat. 1144, 1937 (August 10, 2005) (''SAFETEA''), to administer in certain areas of Indian country (as defined at 18 U.S.C. 1151) the State's environmental regulatory programs that were previously approved by the EPA outside of Indian country.[1] The State's request excluded certain areas of Indian country further described below. In addition, the State only sought approval to the extent that such approval is necessary for the State to administer a program in light of *Oklahoma Dept. of Environmental Quality* v. *EPA,* 740 F.3d 185 (D.C. Cir. 2014).[2]

On October 1, 2020, the EPA approved Oklahoma's SAFETEA request to administer all of the State's EPA-approved environmental regulatory programs, including the Oklahoma SIP, in the requested areas of Indian country.[3] As requested by Oklahoma, the EPA's approval under SAFETEA does not include Indian country lands, including rights-of-way running through the same, that: (1) qualify as Indian allotments, the Indian titles to which have not been extinguished, under 18 U.S.C. 1151(c); (2) are held in trust by the United States on behalf of an individual Indian or Tribe; or (3) are owned in fee by a Tribe, if the Tribe (a) acquired that fee title to such land, or an area that included such land, in accordance with a treaty with the United States to which such Tribe was a party, and (b) never allotted the land to a member or citizen of the Tribe (collectively ''excluded Indian country lands'').

EPA's approval under SAFETEA expressly provided that to the extent EPA's prior approvals of Oklahoma's environmental programs excluded

[1] A copy of the Governor's July 22, 2020, request can be found in the docket for this rulemaking on the *https://www.regulations.gov* website. See Docket ID No. EPA–R06–OAR–2020–0437.

[2] In *ODEQ* v. *EPA,* the D.C. Circuit held that under the CAA, a state has the authority to implement a SIP in non-reservation areas of Indian country in the state, where there has been no demonstration of tribal jurisdiction. Under the D.C. Circuit's decision, the CAA does not provide authority to states to implement SIPs in Indian reservations. *ODEQ* did not, however, substantively address the separate authority in Indian country provided specifically to Oklahoma under SAFETEA. That separate authority was not invoked until the State submitted its request under SAFETEA, and was not approved until EPA's decision, described in this section, on October 1, 2020.

[3] A copy of EPA's October 1, 2020, approval can be found in the docket for this rulemaking on the *https://www.regulations.gov* website. See Docket ID No. EPA–R06–OAR–2020–0437.

Indian country, any such exclusions are superseded for the geographic areas of Indian country covered by the EPA's approval of Oklahoma's SAFETEA request.[4] The approval also provided that future revisions or amendments to Oklahoma's approved environmental regulatory programs would extend to the covered areas of Indian country (without any further need for additional requests under SAFETEA).[5]

As explained above, the EPA is approving revisions to the SIP for Oklahoma submitted by the State of Oklahoma with a letter dated May 7, 2020. Specifically, the action addressed revisions to OAC Title 252 Chapter 100 Subchapter 39, Sections 4, 16, 40, and 41. The revisions corrected errors and made these sections of the Oklahoma SIP consistent with EPA's rules. Consistent with the D.C. Circuit's decision in *ODEQ* v. *EPA* and with EPA's October 1, 2020, SAFETEA approval, this portion of the SIP applies in certain areas of Indian country. Under EPA's October 1, 2020 SAFETEA approval, the SIP revisions approved in this rulemaking action will apply to all Indian country within Tulsa and Oklahoma Counties, other than the excluded Indian country lands, as described above. Because—per the State's request under SAFETEA—EPA's October 1, 2020 approval does not displace any SIP authority previously exercised by the State under the CAA as interpreted in *ODEQ* v. *EPA,* the approved SIP revisions for Oklahoma County and Tulsa County will also apply to any Indian allotments or dependent Indian communities located outside of an Indian reservation over which there has been no demonstration of tribal authority.

[4] EPA's prior approvals relating to Oklahoma's SIP frequently noted that the SIP was not approved to apply in areas of Indian country (consistent with the D.C. Circuit's decision in *ODEQ* v. *EPA*) located in the state. *See, e.g.,* 85 FR 20178, 20180 (April 10, 2020). Such prior expressed limitations are superseded by the EPA's approval of Oklahoma's SAFETEA request.

[5] On December 22, 2021, the EPA proposed to withdraw and reconsider the October 1, 2020, SAFETEA approval. See *https://www.epa.gov/ok/proposed-withdrawal-and-reconsideration-and-supporting-information.* The EPA expects to have further discussions with tribal governments and the State of Oklahoma as part of this reconsideration. The EPA also notes that the October 1, 2020, approval is the subject of a pending challenge in federal court. *Pawnee Nation of Oklahoma* v. *Regan,* No. 20–9635 (10th Cir.). The EPA may make further changes to the approval of Oklahoma's program to reflect the outcome of the proposed withdrawal and reconsideration of the October 1, 2020, SAFETEA approval.

IV. Environmental Justice Considerations

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' [6] The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.'' [7] EPA is providing additional analysis of environmental justice associated with this action. We are doing so for the purpose of providing information to the public, not as a basis of our final action.

EPA reviewed demographic data, which provides an assessment of individual demographic groups of the populations living within the affected Oklahoma and Tulsa counties area.[8] The EPA then compared the data to the national average for each of the demographic groups.[9] The results of the demographic analysis indicate that, for populations within Tulsa and Oklahoma counties, the percent people of color (persons who reported their race as a category other than white alone (not Hispanic or Latino)) is slightly less than the national average for Tulsa County; and slightly more than the national average for Oklahoma County (38 and 44 percent, respectively versus 40 percent). Within people of color, the percent of the population that is Black or African American alone is below the national average for Tulsa County and above the national average for Oklahoma County (10.8 and 15.8 percent, respectively versus 13.4 percent), and the percent of the population that is American Indian/Alaska Native is higher than the national average for both Tulsa and Oklahoma counties (6.9 and 4.4 percent, respectively versus 1.3 percent). The percent of the population that is ''two or more races'' is higher than the national average for both Tulsa and Oklahoma counties (6.2 and 5.4 percent, respectively versus 2.8 percent). The percent of people living below the poverty level in Tulsa and Oklahoma counties is higher than the national average (12.8 and 15.2 percent, respectively versus 11.4 percent). The percent of people over 25 with a high school diploma in Tulsa and Oklahoma counties is similar to the national average (89.9 and 88 percent, respectively versus 88.5 percent), as is the percent with a ''bachelor's degree or higher'' (32 and 33.1 percent, respectively versus 32.9 percent).

The SIP revisions do not appear to have a disproportionately high or adverse human health or environmental effects on communities with EJ concerns as the changes to the Oklahoma SIP will result in updates and clarifications an also further restrict the use of cutback asphalt. Since the use of cutback asphalt is prohibited for a longer period of time each year communities throughout the affected counties will realize benefits.

[6] See *https://www.epa.gov/environmentaljustice/learn-about-environmental-justice.*

[7] *https://www.epa.gov/environmentaljustice/learn-about-environmental-justice.*

[8] See the United States Census Bureau's QuickFacts on Oklahoma at *https://www.census.gov/quickfacts/fact/table/OK,US/PST045221.*

[9] See the United States Census Bureau's QuickFacts on Oklahoma at *https://www.census.gov/quickfacts/fact/table/OK,US/PST045221.*

V. Final Action

We are approving revisions to OAC 252:100–39, Emission of VOCs in Nonattainment Areas and Former Nonattainment Areas, in Section 4 (Exemptions), Section 16 (Petroleum refinery process unit turnaround), Section 40 (Cutback asphalt), and Section 41 (Storage, loading and transport/delivery of VOCs) as submitted to us by a letter dated May 7, 2020 (Submittal). The submittal covers Oklahoma's 2019 regulatory update. This action is being taken under section 110 of the Act.

VI. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference the revisions to the Oklahoma regulations, as described in the Final Action section above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* (please contact the person identified in the **FOR FURTHER**

INFORMATION CONTACT section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated in the next update to the SIP compilation.

VII. Statutory and Executive Order Reviews

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

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

This approval of revisions to the Oklahoma SIP will apply to certain areas of Indian country in Tulsa and Oklahoma Counties, as discussed in the preamble, and therefore has tribal implications as specified in E.O. 13175 (65 FR 67249, November 9, 2000). However, this action will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. This action will not impose substantial direct compliance costs on federally recognized tribal governments because no actions will be required of tribal governments. This action will also not preempt tribal law as no Oklahoma tribe implements a regulatory program under the CAA, and thus does not have applicable or related tribal laws. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes (May 4, 2011), the EPA offered consultation to tribal governments that may be affected by this action. EPA received no comments or requests for consultation from tribal governments.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 27, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 20, 2022.

Earthea Nance,

Regional Administrator, Region 6.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart LL—Oklahoma

■ 2. In § 52.1920 in paragraph (c) amend the table ''EPA APPROVED OKLAHOMA REGULATIONS'' by revising the entries for ''252:100–39–4,'' ''252:100–39–16,'' ''252:100–39–40,'' and ''252:100–39–41'' to read as follows.

* * * * *

(c) * * *

EPA APPROVED OKLAHOMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
OKLAHOMA ADMINISTRATIVE CODE, TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY				
CHAPTER 100 (OAC 252:100). AIR POLLUTION CONTROL				
*	*	*	*	*
Subchapter 39. Emission of Organic Materials in Nonattainment Areas				
Part 1. General Provisions				
*	*	*	*	*
252:100–39–4	Exemptions	9/15/2019	7/29/2022, [Insert **Federal Register** citation].	
Part 3. Petroleum Refinery Operations				
*	*	*	*	*
252:100–39–16	Petroleum refinery process unit turnaround.	9/15/2019	7/29/2022, [Insert **Federal Register** citation].	
*	*	*	*	*
Part 7. Specific Operations				
252:100–39–40	Cutback asphalt (paving)	9/15/2019	7/29/2022, [Insert **Federal Register** citation].	
252:100–39–41	Storage, loading and transport/delivery of VOCs.	9/15/2019	7/29/2022, [Insert **Federal Register** citation].	
*	*	*	*	*

[FR Doc. 2022–16043 Filed 7–28–22; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0623; FRL–8997–02–R9]

Air Plan Approval; Arizona, California, Nevada; Emissions Statements Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions, under the Clean Air Act (CAA or ''Act''), to portions of the Arizona, California, and Nevada State Implementation Plans (SIPs) regarding emissions statements (ES) requirements for the 2015 ozone national ambient air quality standards (NAAQS). We are also taking final action to approve ES certifications (''certifications'') adopted by various California air districts that existing SIP-approved rules are adequate to meet the ES requirements for the 2015 ozone NAAQS. In addition, we are finalizing our proposal that the following Arizona, California, and Nevada nonattainment areas (NAAs) meet the ES requirements for the 2015 ozone NAAQS: Phoenix-Mesa, Yuma, Amador County, Butte County, Imperial County, Los Angeles-San Bernardino Counties (West Mojave Desert), Los Angeles-South Coast Air Basin, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Diego County, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Ventura County, and Las Vegas. We are also finalizing our proposal that two NAAs meet requirements for prior ozone NAAQS. Lastly, we are finalizing our proposal that Maricopa County Air Quality District (MCAQD) Rule 100, section 503, which we approved on February 15, 2022, meets the ES requirements for the 2015 ozone NAAQS.

DATES: This rule is effective August 29, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0623. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please

contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Sina Schwenk-Mueller, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4100 or by email at *SchwenkMueller.Sina@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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II. Public Comments and EPA Responses
III. EPA Action
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I. Proposed Action

On December 14, 2021 (86 FR 70996), the EPA proposed to approve the following rules into their respective state SIPs.

TABLE 1—SUBMITTED RULES

Agency	Rule No.	Rule title	Adopted/ revised	Submitted	Deemed complete
Arizona Department of Environmental Quality (ADEQ).	Arizona Administrative Code (AAC) R18–2–327.	Annual Emissions Inventory Questionnaire and Emissions Statement.	[a] 12/4/2020	12/22/2020	Complete by Operation of Law (COL), 6/22/2020.
Pinal County Air Quality Control District (AQCD).	Rule 3–1–103	Annual Emissions Inventory Questionnaire and Emissions Statement.	7/1/2020	7/21/2020	COL, 1/21/2021.
Amador Air District	Rule 428	Emissions Statements	3/16/2021	6/10/2021	Letter, 9/25/2021.
Butte County Air Quality Management District (AQMD).	Rule 434	Emissions Statements	6/25/2020	7/27/2020	COL, 1/27/2021.
El Dorado County AQMD	Rule 1000	Emission Statement	8/25/2020	9/22/2020	COL, 3/22/2021.
El Dorado County AQMD	Rule 1000.1 [b]	Emission Statement Waiver	8/25/2020	9/22/2020	COL, 3/22/2021.
Feather River AQMD	Rule 4.8	Further Information	8/3/2020	12/15/2020	COL, 6/15/2021.
Imperial County Air Pollution Control District (APCD).	Rule 116	Emissions Statement and Certification.	11/3/2020	2/19/2021	COL, 8/19/2021.
Placer County APCD	Rule 503	Emission Statement	10/8/2020	12/15/2020	COL, 6/15/2021.
San Luis Obispo County AQMD.	Rule 222	Federal Emission Statement	6/24/2020	7/27/2020	COL, 1/27/2021.
Tuolumne County APCD	Rule 428	Emissions Statements	7/21/2020	8/3/2020	COL, 2/3/2021.
Clark County Division of Air Quality.	Section 12.9.1 [c]	Annual Emissions Statement.	[d] 8/18/2020	10/15/2020	COL, 4/15/2021.

[a] The effectiveness date of this rulemaking is 1/19/2021.
[b] Our proposed action incorrectly listed this rule number as 1001.1. The correct rule number is 1000.1.
[c] NDEP submitted Section 12.9 ''Annual Emissions Statement and Inventory Requirements,'' which includes 12.9.1 ''Annual Emissions Statement'' and 12.9.2 and 12.9.3. On 1/24/2022, NDEP withdrew 12.9.2 and 12.9.3 from SIP consideration.
[d] State effective date.

On December 14, 2021 (86 FR 70996), the EPA proposed to approve the following emissions statements certifications into the California SIP.

TABLE 2—SUBMITTED EMISSIONS STATEMENTS CERTIFICATIONS

[2015 Ozone NAAQS] [1]

Local agency	Existing SIP approved Rule No.	Rule title	Adopted	Submitted	Deemed complete
Antelope Valley AQMD	Rule 107 (2012); 78 FR 21545 (April 11, 2013).	Certification of Submissions and Emission Statements.	7/21/2020	8/3/2020	COL, 2/3/2021.
Mojave Desert AQMD	Rule 107 (1992); 69 FR 29880 (May 26, 2004).	Certification and Emission Statements.	10/28/2019	12/20/2019	COL, 6/20/2020.
Northern Sierra AQMD	Rule 513 (2016); 82 FR 28240 (June 21, 2017) [a].	Emissions Statements and Recordkeeping.	1/25/2021	3/23/2021	COL, 9/23/2021.
Sacramento Metropolitan AQMD.	Rule 105 (1996) 73 FR 32240 (June 6, 2008).	Emissions Statement	7/23/2020	8/3/2020	COL, 2/3/2021.
San Diego County APCD	Rule 19.3 (1996); 65 FR 12472 (March 9, 2000).	Emissions Information	10/14/2020	1/12/2021	COL, 7/12/2021.
San Francisco Bay Area AQMD.	Reg 2—Permits 2–1–429 (2004); 83 FR 23372 (May 21, 2018).	Federal Emissions Statement.	7/15/2020	8/3/2020	COL, 2/3/2021.
San Joaquin Valley APCD	Rule 1160 (1992); 84 FR 3302 (February 12, 2019).	Emissions Statements (1992).	6/18/2020	8/3/2020	COL, 2/3/2021.

[1] All certifications in this table were submitted by the State of California. The ''Adopted'' and ''Submitted'' and ''Deemed Complete'' dates listed in Table 2 refer to those of the certifications.

TABLE 2—SUBMITTED EMISSIONS STATEMENTS CERTIFICATIONS—Continued

[2015 Ozone NAAQS] [1]

Local agency	Existing SIP approved Rule No.	Rule title	Adopted	Submitted	Deemed complete
South Coast AQMD	Rule 301 (2019); 84 FR 52005 (October 1, 2019) [b].	Permitting and Associated Fees (paragraphs (e)(1), except (e)(1)(C), (e)(2), (5), and (8) only).	6/5/2020	8/3/2020	COL, 2/3/2021.
Ventura County APCD	Rule 24 (1992); 65 FR 76567 (December 7, 2000).	Source Recordkeeping, Reporting and Emissions Statements.	7/14/2020	7/29/2020	COL, 1/29/2021.
Yolo-Solano AQMD	Rule 3.18 (1992); 69 FR 29880 (May 26, 2004).	Emissions Statements	9/9/2020	11/2/2020	COL, 5/2/2021.

[a] We note that in our December 11, 2017 action, *Findings of Failure to Submit State Implementation Plan Submittals for the 2008 Ozone National Ambient Air Quality Standards (NAAQS)* (82 FR 58118), we erroneously listed the ''Emission statement'' requirement for Nevada County (Western part) in Table 1—Findings of Failure to Submit Certain Required SIP Elements for 2008 Ozone NAAQS Nonattainment Areas.

[b] South Coast AQMD has jurisdiction over Riverside (Coachella), and Rule 301 applies to both the South Coast Air Basin and the Riverside (Coachella) NAAs.

In addition to the certifications for the 2015 ozone NAAQS, the San Francisco Bay Area AQMD is certifying that Reg 2—Permits 2–1–429 meets section 182(a)(3)(B) requirements for the 1997 and 2008 ozone NAAQS, and the San Diego County APCD is certifying that Rule 19.3 meets section 182(a)(3)(B) requirements for the 2008 ozone NAAQS.

We are finalizing approval of these rules and certifications because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on our evaluation of the rules and certifications.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment.

Comment: The commenter expresses support for air pollution control and states that it is important that all the listed counties in our proposal maintain stringent emission standards. However, the commenter is concerned that the SIP is not approved to apply on any Indian reservation or in any other area where a tribe has jurisdiction. The commenter worries that this could provide loopholes to pollute on tribal reservations and wants to know if tribes want to be excluded from state emission control measures.

Response: The comment refers to the EPA's statement that ''the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.'' The EPA typically uses such statements in actions regarding state SIP submittals to explain the non-applicability of the SIP in relevant areas of Indian country as a jurisdictional matter. The States of Arizona, California, and Nevada submitted the rules in this action to apply only on lands where the States and relevant local agencies have jurisdiction. Under the Clean Air Act, states generally lack jurisdiction to implement plans over Indian reservations and other areas of Indian country where the EPA or a tribe has demonstrated tribal jurisdiction. For this reason, the EPA typically excludes such areas from its approvals of SIPs. The commenter's concern regarding the inapplicability of the SIP in areas where an Indian tribe has jurisdiction does not bear upon whether the rules that are the subject of our action meet the applicable requirements for approval of a SIP submission. Therefore, we do not find that the comment provides a basis for the EPA to change its assessment of the submitted rules or our proposal to approve them.

III. EPA Action

No comments were submitted that change our assessment of the rules and certifications as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA fully approves the submitted rules and certifications because they fulfill all relevant requirements. We are finalizing our proposed approval that the following 2015 ozone nonattainment areas have met CAA section 182(a)(3)(B) requirements: Phoenix-Mesa, AZ; Yuma, AZ; Amador County, CA; Butte County, CA; Imperial County, CA; Los Angeles-San Bernardino Counties, CA (West Mojave Desert); Los Angeles-South Coast Air Basin, CA; Nevada County (Western part), CA; Riverside County (Coachella Valley) CA; Sacramento Metro, CA; San Diego County, CA; San Francisco Bay Area, CA; San Joaquin Valley, CA; San Luis Obispo (Eastern part), CA; Sutter Buttes, CA; Tuolumne, County, CA; Ventura County, CA; and Las Vegas, NV. We are also finalizing our proposed approval that the San Francisco Bay Area NAA meets the emissions statements requirements for the 1997 and 2008 ozone NAAQS, and the San Diego County NAA meets these requirements for the 2008 ozone NAAQS. Lastly, we are finalizing our proposal that MCAQD Rule 100, section 503, which the EPA finalized in a separate action on February 15, 2022 (87 FR 8418), meets the emissions statements requirements for the 2015 ozone NAAQS.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the California rules described in section I of this preamble and set forth below in the amendments to 40 CFR part 52. For the States of Arizona and Nevada, the rules described in section I of the preamble and set forth below in the amendments to 40 CFR part 52 have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[2] The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

[2] 62 FR 27968 (May 22, 1997).

V. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 27, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 20, 2022.

Kerry Drake,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends Part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

■ 2. In § 52.120, paragraph (c):

■ a. Amend Table 2 is amended by revising the entry ''R18–2–327''; and

■ b. Amend Table 9 by revising the entry ''3–1–103''.

The revisions read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 2—EPA-APPROVED ARIZONA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Article 3 (Permits and Permit Revisions)				
*	*	*	*	*
R18–2–327	Annual Emissions Inventory Questionnaire and Emissions Statement.	1/19/2021	[INSERT **Federal Register** CITATION], July 29, 2022.	Submitted on December 22, 2020.
*	*	*	*	*

* * * * *

TABLE 9—EPA-APPROVED PINAL COUNTY AIR POLLUTION CONTROL REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Chapter 3. Permits and Permit Revisions				
*	*	*	*	*
3–1–103	Annual emissions inventory questionnaire and emissions statement.	7/1/2020	[INSERT **Federal Register** CITATION], July 29, 2022.	Submitted on July 21, 2020.
*	*	*	*	*

* * * * *

Subpart F—California

■ 3. Section 52.220 is amended by adding paragraphs (c)(190)(i)(C)(*3*), (C)(*4*) and (D)(*2*), (c)(381)(i)(A)(*8*), (c)(389)(i)(B)(*6*), (c)(442)(i)(G)(*2*), (c)(457)(i)(D)(*2*), (c)(562)(i)(A)(*2*), (c)(573), (574), (575), (576), (577), (578), (579), (580), (581), (582) and (583) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(190) * * *

(i) * * *

(C) * * *

(*3*) Previously approved on May 26, 2004 in paragraph (c)(190)(i)(C)(1) of this section and now deleted with replacement in (c)(575)(i)(A)(1), Rule 1000 adopted on September 21, 1992.

(4) Previously approved on May 26, 2004 and added in an error correction on August 29, 2019, in paragraph (c)(190)(i)(C)(2) of this section and now deleted with replacement in (c)(575)(i)(A)(2), Rule 1000.1 adopted on September 21, 1992.

(D) * * *

(*2*) Previously approved on May 26, 2004 in paragraph (c)(190)(i)(D)(1) of this section and now deleted with replacement in (c)(576)(i)(A)(1), Rule 4.8 adopted on September 14, 1992.

* * * * *

(381) * * *

(i) * * *

(A) * * *

(*8*) Previously approved on December 7, 2012 in paragraph (c)(381)(i)(A)(6) of this section and now deleted with replacement in (c)(583)(i)(A)(1), Rule 116, ''Emissions Statement and Certification,'' adopted on February 23, 2010.

* * * * *

(389) * * *

(i) * * *

(B) * * *

(*6*) Previously approved on December 7, 2012 in paragraph (c)(389)(i)(B)(*4*) of this section and now deleted with replacement in (c)(576)(i)(B)(*1*), Rule 503, ''Emission Statement,'' amended on August 12, 2010.

* * * * *

(442) * * *

(i) * * *

(G) * * *

(*2*) Previously approved on June 11, 2015 in paragraph (c)(442)(i)(G)(*1*) of this section and now deleted with replacement in (c)(573)(i)(A)(*1*), Rule 434, ''Emission Statements,'' adopted on April 25, 2013.

* * * * *

(457) * * *

(i) * * *

(D) * * *

(*2*) Previously approved on June 11, 2015 in paragraph (c)(457)(i)(D)(*1*) of this section and now deleted with replacement in (c)(573)(i)(B)(*1*), Rule 222, ''Federal Emission Statement,'' adopted on May 28, 2014.

* * * * *

(562) * * *

(i) * * *

(A) * * *

(*2*) Rule 116, ''Emission Statement and Certification,'' revised on November 3, 2020.

* * * * *

(573) Amended regulations for the following APCDs were submitted on July 27, 2020 by the Governor's designee as an attachment to a letter dated July 23, 2020.

(i) *Incorporation by reference.* (A) Butte County Air Quality Management District.

(*1*) Rule 434, ''Emission Statements,'' amended on June 25, 2020.

(*2*) [Reserved]

(B) San Luis Obispo County Air Pollution Control District.

(*1*) Rule 222, ''Federal Emission Statement,'' revised on June 24, 2020.

(*2*) [Reserved]

(ii) [Reserved]

(574) New and amended regulations and materials for the following APCDs were submitted on August 3, 2020 by the Governor's designee as an attachment to a letter dated August 3, 2020.

(i) *Incorporation by reference.* (A) Tuolumne County Air Pollution Control District.

(*1*) Rule 428, ''Emission Statements,'' adopted on July 21, 2020.

(*2*) [Reserved]

(B) [Reserved]

(ii) *Additional materials.* (A) Antelope Valley Air Quality Management District.

(*1*) ''Emission Statement Certification,'' adopted July 21, 2020.

(*2*) [Reserved]

(B) Sacramento Metropolitan Air Quality Management District.

(*1*) ''Emissions Statements Certification for the 2015 Ozone NAAQS,'' adopted July 23, 2020.

(*2*) [Reserved]

(C) San Francisco Bay Area Air Quality Management District.

(*1*) ''Clean Air Act Emissions Statement Certification,'' adopted July 15, 2020.

(*2*) [Reserved]

(D) San Joaquin Valley Unified Air Pollution Control District.

(*1*) ''Emissions Statement Program Certification for the 2015 8-Hour Ozone Standard,'' adopted June 18, 2020.

(*2*) [Reserved]

(E) South Coast Air Quality Management District.

(*1*) ''Emissions Statement Certification,'' adopted June 5, 2020.

(*2*) [Reserved]

(575) Amended regulations for the following APCDs were submitted on September 22, 2020 by the Governor's designee as an attachment to a letter dated September 18, 2020.

(i) Incorporation by reference.

(A) El Dorado County Air Quality Management District.

(*1*) Rule 1000, ''Emission Statement,'' revised on August 25, 2020.

(*2*) Rule 1000.1, ''Emission Statement Waiver,'' revised on August 25, 2020.

(B) [Reserved]

(ii) [Reserved]

(576) Amended regulations for the following APCDs were submitted on December 15, 2020 by the Governor's designee as an attachment to a letter dated December 14, 2020.

(i) *Incorporation by reference.* (A) Feather River Air Quality Management District.

(*1*) Rule 4.8, ''Further Information,'' amended on August 3, 2020.

(*2*) [Reserved]

(B) Placer County Air Pollution Control District.

(*1*) Rule 503, ''Emission Statement,'' amended on October 8, 2020.

(*2*) [Reserved]

(ii) [Reserved]

(577) Amended regulations for the following APCDs were submitted on June 10, 2021 by the Governor's designee as an attachment to a letter dated June 10, 2021.

(i) Incorporation by reference.

(A) Amador Air District.

(*1*) Rule 428, ''Emissions Statements,'' adopted on March 16, 2021.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

(578) The following plan was submitted on December 20, 2019 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) Mojave Desert Air Quality Management District.

(*1*) ''Emission Statement Certification,'' adopted October 28, 2019.

(*2*) [Reserved]

(B) [Reserved]

(579) The following plan was submitted on July 29, 2020 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.*(A) Ventura County Air Pollution Control District.

(*1*) ''2020 Emissions Statement Certification for Ventura County, California,'' adopted July 14, 2020.

(*2*) [Reserved]

(B) [Reserved]

(580) The following plan was submitted on November 2, 2020 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) Yolo-Solano Air Quality Management District.

(*1*) ''2015 Federal Ozone Standard Emissions Statement Certification for the Yolo-Solano Air Quality Management District,'' adopted September 9, 2020.

(*2*) [Reserved]

(B) [Reserved]

(581) The following plan was submitted on January 12, 2021 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) San Diego County Air Pollution Control District.

(*1*) ''Emissions Statement Rule Certification,'' adopted October 14, 2020.

(*2*) [Reserved]

(B) [Reserved]

(582) The following plan was submitted on March 23, 2021 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) Northern Sierra Air Quality Management District.

(*1*) ''Certification of Emissions Statements Rule Adequacy,'' adopted January 25, 2021.

(*2*) [Reserved]

(B) [Reserved]

(583) Amended regulations for the following APCD were submitted on February 19, 2021 by the Governor's designee as an attachment to a letter dated February 18, 2021.

(i) *Incorporation by reference.* (A) Imperial County Air Pollution Control District.

(*1*) Rule 116, ''Emissions Statement and Certification,'' revised on November 3, 2020.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

Subpart DD—Nevada

■ 4. In § 52.1470, Table 3 is amended by adding an entry for ''Section 12.9.1'' after the entry for ''Section 12.7: Subsection 12.7.5'' to read as follows:

(c) * * *

* * * * *

TABLE 3—EPA-APPROVED CLARK COUNTY REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Section 12.9.1 ...	Annual Emissions Statement	8/18/2020	[INSERT **Federal Register** CITATION], July 29, 2022.	Submitted on October 15, 2020.
*	*	*	*	*

* * * * *

[FR Doc. 2022–16025 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2018–0689; FRL–9654–02–R5]

Air Plan Approval; Minnesota; Approval of Infrastructure SIP Requirements for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving most elements of a State Implementation Plan (SIP) submission from Minnesota regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2015 ozone National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. EPA proposed this action on May 24, 2022 and received no comments.

DATES: This final rule is effective August 29, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2018–0689. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Olivia Davidson, Physical Scientist, at (312) 886–0266 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Olivia Davidson, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0266, *davidson.olivia@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background Information

On May 24, 2022 (87 FR 31462), EPA proposed to approve most elements of an October 1, 2018, submission from the Minnesota Pollution Control Agency (MPCA) intended to address all applicable infrastructure requirements for the 2015 ozone NAAQS. An explanation of the CAA requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking and will not be restated here. The public comment period for this proposed rule ended on June 23, 2022. EPA received no comments on the proposal. Therefore, we are finalizing our action as proposed.

II. Final Action

EPA is approving most elements of a submission from MPCA certifying that its current SIP is sufficient to meet the required infrastructure elements under sections 110(a)(1) and (2) for the 2015 ozone NAAQS. EPA is not acting on the interstate transport requirements of section 110(a)(2)(D)(i)(I) and visibility impairment requirements of section 110(a)(2)(D)(i)(II). EPA's actions for the state's satisfaction of infrastructure SIP requirements, by element of section 110(a)(2), are contained in the table below.

Element	2015 Ozone
(A)—Emission limits and other control measures	A
(B)—Ambient air quality monitoring/data system	A
(C)1—Program for enforcement of control measures	A
(C)2—Minor NSR	A
(C)3—PSD	A
(D)1—I Prong 1: Interstate transport—significant contribution to nonattainment	NA
(D)2—I Prong 2: Interstate transport—interference with maintenance	NA
(D)3—II Prong 3: Interstate transport—interference with PSD	A
(D)4—II Prong 4: Interstate transport—interference with visibility protection	NA
(D)5—Interstate and international pollution abatement	A
(E)1—Adequate resources	A
(E)2—State board requirements	A
(F)—Stationary source monitoring system	A
(G)—Emergency powers	A
(H)—Future SIP revisions	A
(I)—Nonattainment planning requirements of part D	*
(J)1—Consultation with government officials	A
(J)2—Public notification	A
(J)3—PSD	A
(J)4—Visibility protection	*
(K)—Air quality modeling/data	A
(L)—Permitting fees	A
(M)—Consultation/participation by affected local entities	A

In the above table, the key is as follows:

A	Approve.
NA	No Action/Separate Rulemaking.
*	Not germane to infrastructure SIPs.

III. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 27, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 25, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.1220, the table in paragraph (e) is amended by adding an entry at the end of the table for ''Section 110(a)(2) Infrastructure Requirements for the 2015 Ozone NAAQS'' to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED MINNESOTA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approved date	Comments
*	*	*	*	*
Section 110(a)(2) Infrastructure Requirements for the 2015 Ozone NAAQS.	Statewide	10/1/2018	7/29/2022, [INSERT **FEDERAL REGISTER** CITATION].	Fully approved for all CAA elements except (D)(i)(I) and the visibility protection requirements of (D)(i)(II).
*	*	*	*	*

[FR Doc. 2022–16273 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0385; FRL–10027–01–OCSPP]

Isofetamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on multiple commodities discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 29, 2022. Objections and requests for hearings must be received on or before September 27, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0385, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0385 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before September 27, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0385, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2021 (86 FR 58239) (FRL–8792–04–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8913) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to amend 40 CFR part 180.681 to establish tolerances for residues of the fungicide isofetamid, N-[1,1-dimethyl-2-[2-methyl-4-(l-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide including its metabolites and degradates, in or on the raw agricultural commodities ginseng at 3 ppm; individual commodities of Proposed Crop Subgroup 6–XXA: Edible podded bean legume vegetable subgroup at 0.6 ppm; individual commodities of Proposed Crop Subgroup 6–XXB: Edible podded pea legume vegetable subgroup at 1.5 ppm; individual commodities of Proposed Crop Subgroup 6–XXC: Succulent shelled bean subgroup at 0.04 ppm; individual commodities of Proposed Crop Subgroup 6–XXD: Succulent shelled pea subgroup at 0.04 ppm; individual commodities of Proposed Crop Subgroup 6–XXE: Dried shelled bean (except soybean), subgroup at 0.04 ppm; and individual commodities of Proposed Crop Subgroup 6–XXF: Dried shelled pea subgroup at 0.04 ppm. See the October 21, 2021, **Federal Register** notice for the specific commodities. Additionally, the petition requested to remove the established tolerances in or on the raw agricultural commodities: Pea and bean, dried shelled, except soybean, subgroup 6C at 0.040 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.030 ppm; and vegetable, legume, edible podded, subgroup 6A at 1.50 ppm. That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov.*

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the crop group definitions to be consistent with Agency terminology and removing the existing tolerances for Vegetable, legume, edible podded, subgroup 6A; Pea and bean, succulent shelled, subgroup 6B; and Pea and bean, dried shelled, except soybean, subgroup 6C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isofetamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isofetamid follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings in 2015 and 2017 in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to isofetamid and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the 2015 and 2017 rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of isofetamid, see Unit III.A. of the isofetamid tolerance rulemaking published in the **Federal Register** of July 30, 2015 (80 FR 45438) (FRL–9923–86).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for isofetamid used for human risk assessment, please reference Unit III.B. of the July 30, 2015, rulemaking.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of isofetamid on ginseng and the crop group expansions to all the individual bean and pea commodities in proposed crop group 6–XX, which is not yet finalized. An acute dietary exposure assessment was not performed as there are no appropriate toxicological effects attributable to a single exposure (dose). An unrefined chronic aggregate dietary (food and drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined chronic dietary exposure assessment used tolerance-level residues and assumed 100 percent crop treated (PCT) for all registered and proposed commodities. Default processing factors were used for all other proposed and registered processed commodities. Exposure to drinking water was incorporated directly into the dietary assessment. A cancer dietary assessment was not conducted because isofetamid is classified as ''not likely to be carcinogenic to humans.''

Drinking water and non-occupational exposures. The previously recommended estimated drinking water concentrations (EDWCs) remain current and are considered protective potential drinking water residue levels anticipated from the proposed tolerance updates. As stated in the July 30, 2015, rulemaking, the chronic dietary exposure and risk assessment incorporate the highest total estimated drinking water concentrations (EDWC) of 110 parts per billion directly into this dietary assessment. The residential exposure assessment has not changed since the June 14, 2017, rulemaking (82 FR 27149) (FRL–9961–80) because there are no proposed new residential uses. For a summary of the residential exposure analysis for isofetamid used for the human risk assessment, please reference Unit III.C.3. of the June 14, 2017, rulemaking.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for isofetamid and any other substances and isofetamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that isofetamid has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the July 30, 2015, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not performed as there were no appropriate toxicological effects

attributable to a single exposure (dose) observed in available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 4.0% of the cPAD for children 1 to 2 years old, the group with the highest exposure. The combined short-term food, water, and residential exposures result in an aggregate MOE of 670 for children 1 to 2 years old. This MOE is greater than the level of concern of 100 and is therefore not of concern. Isofetamid is classified as ''Not Likely to Be Carcinogenic to Humans''; therefore, EPA does not expect isofetamid exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to isofetamid residues. More detailed information on this action can be found in the document titled ''Isofetamid. Human Health Risk Assessment for the Petition to Establish Permanent Tolerances and Associated Section 3 Registration for Residues Resulting from Proposed Use on Ginseng and for Crop Group Conversions and Expansions.'' in docket ID EPA–HQ–OPP–2021–0385.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 30, 2015, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs for isofetamid in or on ginseng. Presently, there are Codex MRLs established for residues of isofetamid on edible podded beans and peas at 0.6 ppm and on dry beans and peas at 0.09 ppm. The U.S. tolerances of 0.6 ppm for the commodities in the proposed edible podded bean legume subgroup are harmonized with the Codex MRL for edible podded beans. The U.S. tolerances for the edible podded pea commodities at 1.5 ppm are not harmonized with the lower Codex MRL of 0.6 ppm. Harmonization with Codex is not possible for the commodities in the proposed edible podded pea legume vegetable subgroup because decreasing the U.S. tolerance could cause U.S. growers to have violative residues despite legal use of isofetamid according to the label. EPA considered harmonizing the tolerances for dried bean and dried pea commodities with the Codex MRL, but rather elected to be consistent with the Canadian MRL.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid in or on Bean, adzuki, dry seed at 0.04 ppm; Bean, American potato, dry seed at 0.04 ppm; Bean, asparagus, dry seed at 0.04 ppm; Bean, asparagus, edible podded at 0.6 ppm; Bean, black, dry seed at 0.04 ppm; Bean, broad, dry seed at 0.04 ppm; Bean, broad, succulent shelled at 0.04 ppm; Bean, catjang, dry seed at 0.04 ppm; Bean, catjang, edible podded at 0.6 ppm; Bean, catjang, succulent shelled at 0.04 ppm; Bean, cranberry, dry seed at 0.04 ppm; Bean, dry, dry seed at 0.04 ppm; Bean, field, dry seed at 0.04 ppm; Bean, French, dry seed at 0.04 ppm; Bean, French, edible podded at 0.6 ppm; Bean, garden, dry seed at 0.04 ppm; Bean, garden, edible podded at 0.6 ppm; Bean, goa, dry seed at 0.04 ppm; Bean, goa, edible podded at 0.6 ppm; Bean, goa, succulent shelled at 0.04 ppm; Bean, great northern, dry seed at 0.04 ppm; Bean, green, dry seed at 0.04 ppm; Bean, green, edible podded at 0.6 ppm; Bean, guar, dry seed at 0.04 ppm; Bean, guar, edible podded at 0.6 ppm; Bean, kidney, dry seed at 0.04 ppm; Bean, kidney, edible podded at 0.6 ppm; Bean, lablab, dry seed at 0.04 ppm; Bean, lablab, edible podded at 0.6 ppm; Bean, lablab, succulent shelled at 0.04 ppm; Bean, lima, dry seed at 0.04 ppm; Bean, lima, succulent shelled at 0.04 ppm; Bean, morama, dry seed at 0.04 ppm; Bean, moth, dry seed at 0.04 ppm; Bean, moth, edible podded at 0.6 ppm; Bean, moth, succulent shelled at 0.04 ppm; Bean, mung, dry seed at 0.04 ppm; Bean, mung, edible podded at 0.6 ppm; Bean, navy, dry seed at 0.04 ppm; Bean, navy, edible podded at 0.6 ppm; Bean, pink, dry seed at 0.04 ppm; Bean, pinto, dry seed at 0.04 ppm; Bean, red, dry seed at 0.04 ppm; Bean, rice, dry seed at 0.04 ppm; Bean, rice, edible podded at 0.6 ppm; Bean, scarlet runner, dry seed at 0.04 ppm; Bean, scarlet runner, edible podded at 0.6 ppm; Bean, scarlet runner, succulent shelled at 0.04 ppm; Bean, snap, edible podded at 0.6 ppm; Bean, sword, dry seed at 0.04 ppm; Bean, sword, edible podded at 0.6 ppm; Bean, tepary, dry seed at 0.04 ppm; Bean, urd, dry seed at 0.04 ppm; Bean, urd, edible podded at 0.6 ppm; Bean, wax, edible podded at 0.6 ppm; Bean, wax, succulent shelled at 0.04 ppm; Bean, yardlong, dry seed at 0.04 ppm; Bean, yardlong, edible podded at 0.6 ppm; Bean, yellow, dry seed at 0.04 ppm; Chickpea, dry seed at 0.04 ppm; Chickpea, edible podded at 1.5 ppm; Chickpea, succulent shelled at 0.04 ppm; Cowpea, dry seed at 0.04 ppm; Cowpea, edible podded at 0.6 ppm; Cowpea, succulent shelled at 0.04 ppm; Edible podded pea, edible podded at 1.5 ppm; Ginseng at 3 ppm; Gram, horse, dry seed at 0.04 ppm; Grass pea, dry seed at 0.04 ppm; Grass pea, edible podded at 1.5 ppm; Jackbean, dry seed at 0.04 ppm; Jackbean, edible podded at 0.6 ppm; Jackbean, succulent shelled at 0.04 ppm; Lentil, dry seed at 0.04 ppm; Lentil, edible podded at 1.5 ppm; Lentil, succulent shelled at 0.04 ppm; Longbean, Chinese, dry seed at 0.04 ppm; Longbean, Chinese, edible podded at 0.6 ppm; Lupin, Andean, dry seed at 0.04 ppm; Lupin, Andean, succulent shelled at 0.04 ppm; Lupin, blue, dry seed at 0.04 ppm; Lupin, blue, succulent shelled at 0.04 ppm; Lupin, grain, dry seed at 0.04 ppm; Lupin, grain, succulent shelled at 0.04 ppm; Lupin, sweet white, dry seed at 0.04 ppm; Lupin, sweet white, succulent shelled at 0.04 ppm; Lupin, sweet, dry seed at 0.04 ppm; Lupin, sweet, succulent shelled at 0.04 ppm; Lupin, white, dry seed at 0.04 ppm; Lupin, white, succulent shelled at 0.04 ppm; Lupin, yellow, dry seed at 0.04 ppm; Lupin, yellow, succulent shelled at 0.04 ppm; Pea, blackeyed, succulent shelled at 0.04 ppm; Pea, crowder, dry seed at 0.04 ppm; Pea, crowder, succulent shelled at 0.04 ppm; Pea, dry, dry seed at 0.04 ppm; Pea, dwarf, edible podded at 1.5 ppm; Pea, English, succulent shelled at 0.04 ppm; Pea, field, dry seed at 0.04 ppm; Pea, garden, dry seed at 0.04 ppm; Pea, garden, succulent shelled at 0.04 ppm; Pea, green, dry seed at 0.04 ppm; Pea, green, edible podded at 1.5 ppm; Pea, green, succulent shelled at 0.04 ppm; Pea, pigeon, dry seed at 0.04 ppm; Pea, pigeon, edible podded at 1.5 ppm; Pea, pigeon, succulent shelled at 0.04 ppm; Pea, snap, edible podded at 1.5 ppm; Pea, snow, edible podded at 1.5 ppm; Pea, southern, succulent shelled at 0.04 ppm; Pea, sugar snap, edible podded at 1.5 ppm; Pea, winged, dry seed at 0.04 ppm; Pea, winged, edible podded at 0.6 ppm; Soybean, vegetable, dry seed at 0.04 ppm; Soybean, vegetable, edible podded at 0.6 ppm; Soybean, vegetable, succulent shelled at 0.04 ppm; Velvetbean, dry seed at 0.04 ppm; Velvetbean, edible podded at 0.6 ppm; Velvetbean, succulent shelled at 0.04

ppm; and Yam bean, African, dry seed at 0.04 ppm.

Additionally, the existing tolerances on Vegetable, legume, edible podded, subgroup 6A; Pea and bean, succulent shelled, subgroup 6B; and Pea and bean, dried shelled, except soybean, subgroup 6C are removed as unnecessary since they are covered by the new tolerances established in this rulemaking.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: July 21, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1.The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Amend § 180.681 by revising the table in paragraph (a) to read as follows:

§ 180.681 Isofetamid; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond	0.01
Almond, hulls	0.01
Apple, wet pomace	2.0
Bean, adzuki, dry seed	0.04
Bean, American potato, dry seed	0.04
Bean, asparagus, dry seed	0.04
Bean, asparagus, edible podded	0.6
Bean, black, dry seed	0.04
Bean, broad, dry seed	0.04
Bean, broad, succulent shelled	0.04
Bean, catjang, dry seed	0.04
Bean, catjang, edible podded	0.6
Bean, catjang, succulent shelled	0.04
Bean, cranberry, dry seed	0.04
Bean, dry, dry seed	0.04
Bean, field, dry seed	0.04
Bean, French, dry seed	0.04
Bean, French, edible podded	0.6
Bean, garden, dry seed	0.04
Bean, garden, edible podded	0.6
Bean, goa, dry seed	0.04
Bean, goa, edible podded	0.6
Bean, goa, succulent shelled	0.04
Bean, great northern, dry seed	0.04
Bean, green, dry seed	0.04
Bean, green, edible podded	0.6
Bean, guar, dry seed	0.04
Bean, guar, edible podded	0.6
Bean, kidney, dry seed	0.04
Bean, kidney, edible podded	0.6
Bean, lablab, dry seed	0.04
Bean, lablab, edible podded	0.6
Bean, lablab, succulent shelled	0.04
Bean, lima, dry seed	0.04
Bean, lima, succulent shelled	0.04
Bean, morama, dry seed	0.04
Bean, moth, dry seed	0.04
Bean, moth, edible podded	0.6
Bean, moth, succulent shelled	0.04
Bean, mung, dry seed	0.04
Bean, mung, edible podded	0.6
Bean, navy, dry seed	0.04
Bean, navy, edible podded	0.6
Bean, pink, dry seed	0.04
Bean, pinto, dry seed	0.04
Bean, red, dry seed	0.04
Bean, rice, dry seed	0.04
Bean, rice, edible podded	0.6
Bean, scarlet runner, dry seed	0.04
Bean, scarlet runner, edible podded	0.6
Bean, scarlet runner, succulent shelled	0.04
Bean, snap, edible podded	0.6
Bean, sword, dry seed	0.04
Bean, sword, edible podded	0.6
Bean, tepary, dry seed	0.04
Bean, urd, dry seed	0.04
Bean, urd, edible podded	0.6
Bean, wax, edible podded	0.6
Bean, wax, succulent shelled	0.04
Bean, yardlong, dry seed	0.04
Bean, yardlong, edible podded	0.6

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Bean, yellow, dry seed	0.04
Berry, low growing, subgroup 13–07G	4.0
Bushberry subgroup 13–07B	5.0
Caneberry subgroup 13–07A	4.0
Canola, refined oil	0.03
Cherry subgroup 12–12A	4.0
Chickpea, dry seed	0.04
Chickpea, edible podded	1.5
Chickpea, succulent shelled	0.04
Cowpea, dry seed	0.04
Cowpea, edible podded	0.6
Cowpea, succulent shelled	0.04
Edible podded pea, edible podded	1.5
Flax, seed, oil	0.03
Fruit, pome, group 11–10	0.60
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	3.0
Fruit, small vine climbing, except grape, subgroup 13–07E	10.0
Ginseng	3
Gram, horse, dry seed	0.04
Grape, raisin	5.0
Grass pea, dry seed	0.04
Grass pea, edible podded	1.5
Jackbean, dry seed	0.04
Jackbean, edible podded	0.6
Jackbean, succulent shelled	0.04
Lentil, dry seed	0.04
Lentil, edible podded	1.5
Lentil, succulent shelled	0.04
Lettuce, head	5.0
Lettuce, leaf	7.0
Longbean, Chinese, dry seed	0.04
Longbean, Chinese, edible podded	0.6
Lupin, Andean, dry seed	0.04
Lupin, Andean, succulent shelled	0.04
Lupin, blue, dry seed	0.04
Lupin, blue, succulent shelled	0.04
Lupin, grain, dry seed	0.04
Lupin, grain, succulent shelled	0.04
Lupin, sweet white, dry seed	0.04
Lupin, sweet white, succulent shelled	0.04
Lupin, sweet, dry seed	0.04
Lupin, sweet, succulent shelled	0.04
Lupin, white, dry seed	0.04
Lupin, white, succulent shelled	0.04
Lupin, yellow, dry seed	0.04
Lupin, yellow, succulent shelled	0.04
Mustard, seed, oil	0.03
Pea, blackeyed, succulent shelled	0.04
Pea, crowder, dry seed	0.04
Pea, crowder, succulent shelled	0.04
Pea, dry, dry seed	0.04
Pea, dwarf, edible podded	1.5

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Pea, English, succulent shelled	0.04
Pea, field, dry seed	0.04
Pea, garden, dry seed	0.04
Pea, garden, succulent shelled	0.04
Pea, green, dry seed	0.04
Pea, green, edible podded	1.5
Pea, green, succulent shelled	0.04
Pea, pigeon, dry seed	0.04
Pea, pigeon, edible podded	1.5
Pea, pigeon, succulent shelled	0.04
Pea, snap, edible podded	1.5
Pea, snow, edible podded	1.5
Pea, southern, succulent shelled	0.04
Pea, sugar snap, edible podded	1.5
Pea, winged, dry seed	0.04
Pea, winged, edible podded	0.6
Peach subgroup 12–12B	3.0
Plum subgroup 12–12C	0.80
Plum, Prune, Dried	1.50
Rapeseed subgroup 20A	0.015
Sesame, oil	0.03
Soybean, vegetable, dry seed	0.04
Soybean, vegetable, edible podded	0.6
Soybean, vegetable, succulent shelled	0.04
Velvetbean, dry seed	0.04
Velvetbean, edible podded	0.6
Velvetbean, succulent shelled	0.04
Yam bean, African, dry seed	0.04

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1773–F]

RIN 0938–AU83

Medicare Program; FY 2023 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule updates the hospice wage index, payment rates, and aggregate cap amount for Fiscal Year (FY) 2023. This final rule establishes a permanent mitigation policy to smooth the impact of year-to-year changes in hospice payments related to changes in the hospice wage index. In addition, this rule updates the Hospice Quality Reporting Program (HQRP) and discusses further development of the Hospice Outcomes and Patient Evaluation (HOPE) assessment instrument; updates the Quality Measures (QMs) that will be in effect in FY 2023 for the HQRP and future QMs; updates the Consumer Assessment of Healthcare Providers and Systems, Hospice Survey Mode Experiment, discusses a request for information on health equity, and updates the hospice survey and enforcement procedures.

DATES: These regulations are effective on October 1, 2022.

FOR FURTHER INFORMATION CONTACT:

For general questions about hospice payment policy, send your inquiry via email to: *hospicepolicy@cms.hhs.gov.*

For questions regarding the CAHPS® Hospice Survey, contact Lori Teichman at (410) 786–6684 and Lauren Fuentes at (410) 786–2290.

For questions regarding the hospice quality reporting program, contact Cindy Massuda at (410) 786–0652.

For information regarding the hospice special focus program, send your inquiry via email to *QSOG_hospice@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This final rule updates the hospice wage index, hospice payment rates, and aggregate cap amount for FY 2023, as required under section 1814(i) of the Social Security Act (the Act). This rule also finalizes the permanent mitigation policy to smooth the impact of year-to-year changes in hospice payments related to changes in the hospice wage index. In addition, in this final rule, CMS discusses updates to the Hospice Quality Reporting Program (HQRP) that include the Hospice Outcomes and Patient Evaluation (HOPE) with national beta testing; the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospice Survey with Star Ratings; developing a web-based survey; Public Reporting; a request for information that builds from last year's discussion on health equity, updates on advancing a health information exchange, and updates on hospice survey and enforcement procedures.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that

recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. Hospice provides compassionate beneficiary and family/caregiver-centered care for those who are terminally ill.

As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. The regulations at § 418.22(b)(2) require that clinical information and other documentation that support the medical prognosis accompany the certification and be filed in the medical record with it. Additionally, the regulations at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

Under the Medicare hospice benefit, once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group (IDG) is essential in ensuring the provision of primarily home-based services, keeping the choices of the patient and family first and foremost. The hospice IDG works with the beneficiary, family, and caregiver(s) to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition and care. The beneficiary's care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) as the individual approaches the end of life.

If, in the judgment of the hospice IDG, which includes the hospice physician, the patient's symptoms cannot be effectively managed at home, then the patient is eligible for general inpatient care (GIP), a more medically intense level of care. GIP must be provided in a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital. GIP is provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to their home and continue to receive routine home care (RHC). Limited, short-term, intermittent, inpatient respite care (IRC) is also available to provide relief for the family or other caregivers, or when the family or other caregivers are absent. Additionally, an individual can receive continuous home care (CHC) during a period of crisis, in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. CHC may be covered for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with the regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the CHC rate (§ 418.302(e)(4)).

Hospices must comply with applicable civil rights laws,[1] including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. In addition, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: *http://www.hhs.gov/ocr/civilrights.*

[1] Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, Section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

B. Services Covered by the Medicare Hospice Benefit

Coverage under the Medicare hospice benefit requires that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare-certified hospice program. These covered services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); continuous home care during periods of crisis, and only as necessary to maintain the terminally ill individual at home; and any other item or service, which is specified in the plan of care and for which payment may otherwise be made under Medicare in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, the hospice program; and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

Upon the implementation of the hospice benefit, the Congress also expected hospices to continue to use volunteer services, though Medicare does not pay for these volunteer services (section 1861(dd)(2)(E) of the Act). As stated in the FY 1983 Hospice Wage Index and Rate Update proposed rule (48 FR 38149), the hospice must have an interdisciplinary group composed of paid hospice employees as well as hospice volunteers, and that ''the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices.'' This expectation supports the hospice philosophy of community based, holistic,

comprehensive, and compassionate end of life care.

C. Medicare Payment and Quality for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and the regulations in 42 CFR part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment based on one of four prospectively-determined rate categories of hospice care (RHC, CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is meant to cover all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act.

While recent news reports [2] have brought to light the potential role hospices could play in medical aid in dying (MAID) where such practices have been legalized in certain states, we wish to remind hospices that the Assisted Suicide Funding Restriction Act of 1997 (Pub. L. 105–12) prohibits the use of Federal funds to provide or pay for any health care item or service or health benefit coverage for the purpose of causing, or assisting to cause, the death of any individual including mercy killing, euthanasia, or assisted suicide. This means that while payments made to hospices are to cover all items, services, and drugs for the palliation and management of the terminal illness and related conditions, Federal funds cannot be used for the prohibited activities, even in the context of a per diem payment. However, the prohibition does not pertain to the provision of an item or service for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as the item or service is not furnished for the specific purpose of causing or accelerating death.

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) amended section 1814(i)(1)(C) of the Act and provided changes in the methodology concerning updating the daily payment rates based on the hospital market basket percentage increase applied to the payment rates in effect during the previous Federal fiscal year.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established that updates to the hospice payment rates beginning FY 2002 and in subsequent FYs are to be the hospital market basket percentage increase for the current FY. Section 4442 of the BBA amended section 1814(i)(2) of the Act, effective for services furnished on or after October 1, 1997, to require that hospices submit claims for payment for hospice care furnished in an individual's home only on the basis of the geographic location at which the service is furnished. Previously, local wage index values were applied based on the geographic location of the hospice provider, regardless of where the hospice care was furnished. Section 4443 of the BBA amended sections 1812(a)(4) and 1812(d)(1) of the Act to provide for hospice benefit periods of two 90-day periods, followed by an unlimited number of 60-day periods.

3. FY 1998 Hospice Wage Index Final Rule

The FY 1998 Hospice Wage Index final rule (62 FR 42860) implemented a new methodology for calculating the hospice wage index and instituted an annual Budget Neutrality Adjustment Factor (BNAF) so aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index.

4. FY 2010 Hospice Wage Index Final Rule

The FY 2010 Hospice Wage Index and Rate Update final rule (74 FR 39384) instituted an incremental 7-year phase-out of the BNAF beginning in FY 2010 through FY 2016. The BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value, but was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act are subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) of the Act.

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures specified by the Secretary of the Department of Health and Human Services (the Secretary) for FY 2014 and subsequent FYs. Since FY 2014, hospices that fail to report quality data have their market basket percentage increase reduced by 2 percentage points. Note that with the passage of the Consolidated Appropriations Act, 2021 (hereafter referred to as CAA 2021) (Pub. L. 116–260), the reduction changes to 4 percentage points beginning in FY 2024.

Section 1814(a)(7)(D)(i) of the Act, as added by section 3132(b)(2) of the PPACA, required, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, the Centers for Medicare & Medicaid Services (CMS) finalized in the FY 2011 Hospice Wage Index final rule (75 FR 70435) that the 180th day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the PPACA, authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the ACA could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data collected could be used to revise the methodology for determining the payment rates for RHC and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, CMS was required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

In the FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) we announced that beginning in 2012, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology, within certain limits. Existing hospices had the

[2] Nelson, R., Should Medical Aid in Dying Be Part of Hospice Care? Medscape Nurses. February 26, 2020. *https://www.medscape.com/viewarticle/925769#vp_1.*

option of having their cap calculated through the original streamlined methodology, also within certain limits. As of FY 2012, new hospices have their cap determinations calculated using the patient-by-patient proportional methodology. If a hospice's total Medicare payments for the cap year exceed the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

7. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days of care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment percentage update rather than using the consumer price index for urban consumers (CPI–U) for medical care expenditures.

8. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50452) finalized a requirement that the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). As with the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation within 5 calendar days after the effective date of the discharge/revocation (unless the hospice has already filed a final claim) through the submission of a final claim or a Notice of Termination or Revocation (NOTR).

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50479) also finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians.

In addition, the FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50496) provided background, described eligibility criteria, identified survey respondents, and otherwise implemented the Hospice Experience of Care Survey for informal caregivers. Hospice providers were required to begin using this survey for hospice patients as of 2015.

Finally, the FY 2015 Hospice Wage Index and Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that fail to submit their aggregate cap determinations on a timely basis will have their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47142), CMS finalized two different payment rates for RHC: a higher per diem base payment rate for the first 60 days of hospice care and a reduced per diem base payment rate for subsequent days of hospice care. CMS also finalized a service intensity add-on (SIA) payment payable for certain services during the last 7 days of the beneficiary's life. A service intensity add-on payment will be made for the social worker (SW) visits and nursing visits provided by a registered nurse (RN), when provided during routine home care in the last 7 days of life. The SIA payment is in addition to the routine home care rate. The SIA payment is provided for visits of a minimum of 15 minutes and a maximum of 4 hours per day (80 FR 47172).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Rate Update final rule implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016 and before October 1, 2025 would be updated by the hospice payment update percentage rather than using the CPI–U (80 FR 47186). In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the FY for FY 2017 and thereafter. Finally, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47144) clarified that hospices would have to report all diagnoses on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52160), CMS finalized several new policies and requirements related to the HQRP. First, CMS codified the policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQRP measures as part of the NQF's re-endorsement process, CMS would continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking. CMS would continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures adopted for the HQRP; determinations about what constitutes a substantive versus non-substantive change would be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQRP for the FY 2019 payment determination and subsequent years: (1) Hospice Visits when Death is Imminent Measure Pair; and (2) Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission (81 FR 52173). The data collection mechanism for both of these measures is the Hospice Item Set (HIS), and the measures were effective April 1, 2017. Regarding the CAHPS® Hospice Survey, CMS finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice CAHPS® requirements due to newness (81 FR 52182). The exemption is determined by CMS and is only for 1 year.

11. FY 2020 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38484), we finalized rebased payment rates for CHC and GIP and set those rates equal to their average estimated FY 2019 costs per day. We also rebased IRC per diem rates equal to the estimated FY 2019 average costs per day, with a reduction of 5 percent to the FY 2019 average cost per day to account for coinsurance. We finalized the FY 2020 proposal to reduce the RHC payment rates by 2.72 percent to offset the increases to CHC, IRC, and GIP payment rates to implement this policy in a budget-neutral manner in accordance with section 1814(i)(6) of the Act (84 FR 38496).

In addition, we finalized a policy to use the current year's pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. Finally, in the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38505), we finalized modifications to the hospice election statement content requirements at § 418.24(b), and added a requirement for hospices, upon request, to furnish an election statement addendum effective beginning in FY 2021. The addendum must list items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions, to increase coverage transparency for beneficiaries under a hospice election.

12. Consolidated Appropriations Act, 2021

Division CC, section 404 of the CAA 2021 amended section 1814(i)(2)(B) of the Act and extended the provision that currently mandates the hospice cap be updated by the hospice payment update percentage (hospital market basket update reduced by the productivity adjustment) rather than the CPI–U for accounting years that end after September 30, 2016 and before October 1, 2030. Prior to enactment of this provision, the hospice cap update was set to revert to the original methodology of updating the annual cap amount by the CPI–U beginning on October 1, 2025. Division CC, section 407(b) of CAA 2021 revised section 1814(i)(5)(A)(i) to increase the payment reduction for hospices who fail to meet hospice quality measure reporting requirements from 2 percentage points to 4 percentage points beginning with FY 2024.

13. FY 2022 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2022 Hospice Wage Index and Rate Update final rule (86 FR 42532 through 42539), we finalized a policy to rebase and revise the labor shares for CHC, RHC, IRC and GIP using Medicare cost report (MCR) data for freestanding hospices (collected via CMS Form 1984–14, OMB NO. 0938–0758) for 2018. We established separate labor shares for CHC, RHC, IRC, and GIP based on the calculated compensation cost weights for each level of care from the 2018 MCR data. The revised labor shares were implemented in a budget neutral manner through the use of labor share standardization factors.

In the FY 2022 final rule, we removed the seven original Hospice Item Set (HIS) measures from the program because a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available and already publicly reported. The Hospice Comprehensive Assessment Measure, NQF #3235, is one measure that is calculated and rolled up by completion of the seven individual measures. This measure helps to ensure all hospice patients receive a holistic comprehensive assessment. Also, in or after May 2022, we will start publicly reporting the two new claims-based measures. Specifically, this includes the: (1) Hospice Visits in the Last Days of Life (HVLDL) (which replaces the HIS Hospice Visits when Death is Imminent measure pair); and (2) Hospice Care Index (HCI) that includes 10 indicators that collectively represent different aspects of hospice care and aim to convey a comprehensive characterization of the quality of care furnished by a hospice throughout the hospice stay. Related to these changes, we finalized reporting eight quarters of claims data in order to display small providers. We finalized the public reporting of Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey Star ratings on Care Compare to begin no sooner than FY 2022.

III. Analysis of and Responses to Public Comments

We received approximately 73 comments from stakeholders including national hospice associations, state associations, hospices, health systems, electronic health record vendors, and individuals. We reviewed each commenter's letter and grouped related comments. Some comments were identical. After associating like comments, we placed them in categories based on subject matter or based on the section(s) of the regulation affected. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

IV. Provisions of the Final Rule

A. FY 2023 Hospice Wage Index and Rate Update

1. FY 2023 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospices under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.* In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area (CSA), and changes to New England City and Town Area (NECTA) delineations. In the FY 2021 Hospice Wage Index final rule (85 FR 47070) we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in future rulemaking. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in the FY 2021 Hospice Wage Index final rule (85 FR 47070), we include hospitals located in Micropolitan Statistical areas in each state's rural wage index.

In the FY 2020 Hospice Wage Index final rule (84 FR 38484), we finalized the proposal to use the current FY's hospital wage index data to calculate the hospice wage index values. In the FY 2021 Hospice Wage Index final rule (85 FR 47070), we adopted the revised OMB delineations with a 5-percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5-percent in FY 2021 and no cap would be applied to wage index decreases for

the second year (FY 2022). For FY 2023, the final hospice wage index will be based on the FY 2023 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2018 and before October 1, 2019 (FY 2019 cost report data). The final FY 2023 hospice wage index will not take into account any geographic reclassification of hospitals, including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The FY 2023 hospice wage index will include a 5-percent cap on wage index decreases, as discussed later in this section. The appropriate wage index value would be applied to the labor portion of the hospice payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or IRC.

In the FY 2006 Hospice Wage Index final rule (70 FR 45135), we adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the CBSAs within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas. For FY 2023, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia. The FY 2023 final wage index value for Hinesville-Fort Stewart, Georgia is 0.8628.

There exist some geographic areas where there were no hospitals, and thus, no hospital wage data on which to base the calculation of the hospice wage index. In the FY 2008 Hospice Wage Index final rule (72 FR 50217 through 50218), we implemented a methodology to update the hospice wage index for rural areas without hospital wage data. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs, to represent a reasonable proxy for the rural area. The term ''contiguous'' means sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity of almost all of Puerto Rico's various urban areas to non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For FY 2023, we proposed to continue using the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047, subsequently adjusted by the hospice floor.

As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are subject to application of the hospice floor to compute the hospice wage index used to determine payments to hospices. As previously discussed, the pre-floor, pre-reclassified hospital wage index values below 0.8 will be further adjusted by a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor, pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15, which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

The final hospice wage index applicable for FY 2023 (October 1, 2022 through September 30, 2023) is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html.*

We received 8 comments on the proposed FY 2023 hospice wage index from various stakeholders including hospices and national industry associations. A summary of these comments and our responses to those comments are as follows:

Comment: A few commenters expressed concerns regarding the CBSA designation of Montgomery County, Maryland and its associated wage index value. These commenters stated that hospices in Montgomery County, Maryland are at a disadvantage because they are not included in the Washington-Arlington-Alexandria, DC-VA-MD-WV CBSA (CBSA 47894). Two commenters requested that CMS reconsider the Frederick-Gaithersburg-Rockville, Maryland metropolitan division to resolve the hospice payment inequity in Montgomery County. Another commenter recommended three possible solutions to resolve the wage index issue they believe exists in Montgomery County, Maryland. These recommended solutions include: CMS assigning the District of Columbia (DC) hospice wage index valuation to the Montgomery/Frederick County CBSA; CMS assigning the highest wage index valuation from among the MSAs' metropolitan divisions, also known as CBSAs, for the purpose of hospice Medicare reimbursement; CMS pursuing either option for a time limited period, such as 5 years, in order to evaluate the impact on Montgomery County hospices.

Response: We thank the commenters for these recommendations. However, we have used CBSAs for determining hospice payments since FY 2006, and continue to believe that the OMB's geographic area delineations represent a useful proxy for differentiating between labor markets and that the geographic area delineations are appropriate for use in determining Medicare hospice payments. CBSAs provide a uniform and consistent basis for determining statistical area delineations, based on long-standing statistical standards maintained by OMB. Further, OMB conducts periodic review of the standards to ensure their continued usefulness and relevance. Additionally, other provider types, such as Inpatient Prospective Payment System (IPPS) hospitals, home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and dialysis facilities, all use CBSAs to define their labor market areas. Therefore, we believe it is important to apply this method consistently among providers. Using the most current OMB delineations provides an accurate representation of geographic variation in wage levels; therefore, we do not believe it would be appropriate to allow hospices to be assigned a higher CBSA designation or to allow a 5-year limited increase in hospice wage index payments for hospices only in the Montgomery County Metropolitan Divisions. However, if Montgomery County is ever redesignated into CBSA 47894, we would propose this change in future rulemaking consistent with our longstanding approach of adopting OMB statistical area delineations outlined in the most recent OMB bulletins.

Comment: One commenter stated that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting hospice and home health costs, particularly in states that have the nation's highest labor costs. The commenter stated that these costs will never be adequately addressed if CMS continues to use the pre-floor, pre-reclassified hospital wage index to

adjust hospice and home health costs. Several commenters recommended more far-reaching revisions and reforms to the wage index methodology used under Medicare fee-for-service, such as instituting a policy that no hospice be paid below the rural floor for their state or considering a rural floor for hospices that exceed a 3 percent or greater gap between their urban versus average rural rate. Other commenters recommended that CMS allow hospices and other post-acute providers to utilize a reclassification board similar to hospitals. Another commenter suggested that CMS revisit MedPAC's 2007 proposal, which recommended that the Congress repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary authority to establish new wage index systems.

Response: We appreciate the commenters' recommendations; however, these comments are outside the scope of the proposed rule. Any changes regarding the adjustment of the hospice payments to account for geographic wage differences, beyond the wage index proposals discussed in the FY 2023 Hospice Wage Index and Rate Update proposed rule, would have to go through notice and comment rulemaking. While CMS and other interested parties, such as MedPAC, have explored potential alternatives to the current CBSA-based labor market system, no consensus has been achieved regarding how best to implement a replacement system. We believe that in the absence of hospice specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for hospice payments.

Additionally, the regulations that govern hospice payment do not provide a mechanism for allowing hospices to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. The reclassification provision found in section 1886(d)(10) of the Act is specific to hospitals. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This rural floor provision is also specific to hospitals. Because the reclassification provision and the hospital rural floor applies only to hospitals, and not to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results is the most appropriate adjustment to the labor portion of the hospice payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and HH PPS). However, the hospice wage index does include the hospice floor which is applicable to all CBSAs, both rural and urban. The hospice floor adjusts pre-floor, pre-reclassified hospital wage index values below 0.8 by a 15 percent increase subject to a maximum wage index value of 0.8.

Final Decision: We are finalizing our proposal to use the FY 2023 pre-floor, pre-reclassified hospital wage index data as the basis for the FY 2023 hospice wage index. The wage index applicable for FY 2023 is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/Hospice/Hospice-Wage-Index.* The hospice wage index for FY 2023 is effective October 1, 2022 through September 30, 2023.

2. Permanent Cap on Wage Index Decreases

As discussed in this section, we have proposed and finalized temporary transition policies in the past to mitigate significant changes to payments due to changes to the hospice wage index. Specifically, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142) we implemented a 50/50 blend for all geographic areas consisting of the wage index values using the then-current OMB area delineations and the wage index values using OMB's new area delineations based on OMB Bulletin No. 13–01. In the FY 2021 Hospice Wage Index final rule (85 FR 47070), we adopted the revised OMB delineations with a 5-percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5-percent in FY 2021 and no cap would be applied to wage index decreases for the second year (FY 2022). As explained, we believed the 5-percent cap would provide greater transparency and be administratively less complex than the prior methodology of applying a 50/50 blended wage index. We noted that this transition approach struck an appropriate balance by providing a transition period to mitigate the resulting short-term instability and negative impacts on providers and time for them to adjust to their new labor market area delineations and wage index values.

In the FY 2022 Hospice Wage Index and Payment Rate Update final rule (86 FR 42541), a few commenters stated that providers should be protected against substantial payment reductions due to dramatic reductions in wage index values from one year to the next. Because we did not propose to modify the transition policy that was finalized in the FY 2021 Hospice final rule, we did not extend the transition period for FY 2022. In the FY 2022 Hospice final rule, we stated that we continued to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions associated with the adoption of the revised CBSA delineations in FY 2021, allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in hospice payments and improving the accuracy of the payment adjustment for differences in area wage levels. However, we acknowledged that certain changes to wage index policy may significantly affect Medicare payments. In addition, we reiterated that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking. With these policy principles in mind, we considered for the FY 2023 Hospice proposed rule how best to address the potential scenarios about which commenters raised concerns; that is, scenarios in which changes to wage index policy may significantly affect Medicare payments.

In the past, we have established transition policies of limited duration to phase in significant changes to labor market areas. In taking this approach in the past, we sought to mitigate short term instability and fluctuations that can negatively impact providers due to wage index changes. In accordance with the requirement of our regulations at § 418.306(c) each labor market is established using the most current hospital wage data available, including any changes made by the OMB to the Metropolitan Statistical Areas (MSAs) definitions. We have previously stated that, because the wage index is a relative measure of the value of labor in prescribed labor market areas, we believe it is important to implement new labor market area delineations with as minimal a transition as is reasonably possible. However, we recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain providers even when labor market areas do not change. In addition, year-to-year fluctuations in an area's wage index can

occur due to external factors beyond a provider's control, such as the COVID–19 public health emergency (PHE), and for an individual provider, these fluctuations can be difficult to predict. We also recognize that predictability in Medicare payments is important to enable providers to budget and plan their operations.

In light of these considerations, for FY 2023 and subsequent years, we proposed to apply a permanent 5-percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we proposed that a geographic area's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index would not be less than 95 percent of its wage index calculated in the prior FY. We further proposed that if a geographic area's prior FY wage index is calculated based on the 5-percent cap, then the following year's wage index would not be less than 95 percent of the geographic area's capped wage index in the prior FY. For example, if a geographic area's wage index for FY 2023 is calculated with the application of the 5-percent cap, then its wage index for FY 2024 would not be less than 95 percent of its capped wage index in FY 2023. Likewise, we proposed to make the corresponding regulations text changes at § 418.306(c) as follows: starting on October 1, 2022, CMS applies a cap on decreases to the hospice wage index such that the wage index applied to a geographic area is not less than 95 percent of the wage index applied to that geographic area in the prior FY. This 5-percent cap on negative wage index changes would be implemented in a budget neutral manner through the use of wage index standardization factors. Furthermore, the 5-percent cap would be applied after the application of the hospice wage index floor. Therefore, pre-floor, pre-reclassified hospital wage index values below 0.8 would be adjusted by the 15 percent increase, subject to a maximum wage index value of 0.8. If there is a 5-percent decrease from the previous FY's wage index value after the application of the hospice wage index floor, then the 5-percent cap on wage index decreases would also be applied. We stated that we believe that applying a 5-percent cap on all wage index decreases, from the prior year, would have a small overall impact on the labor market area wage index system. We estimate that applying a 5-percent cap on all wage index decreases, from the prior year, will have a very small effect on the wage index budget standardization factors for FY 2023. Because the wage index is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average, we anticipate that most providers will not experience year-to-year wage index declines greater than 5-percent in any given year. We believe that applying a 5-percent cap on all wage index decreases, from the prior year, would continue to maintain the accuracy of the overall labor market area wage index system.

In section III.A.4 of this final rule, we estimate the impact to payments for providers in FY 2023 based on this final policy. We also note that we would examine the effects of this policy on an ongoing basis in the future in order to assess its appropriateness.

We received 23 comments on the proposed permanent cap on wage index decreases. A summary of these comments and our responses to those comments are as follows:

Comment: The majority of commenters expressed support for the proposal to cap wage index decreases at 5 percent.

Response: We thank the commenters for their support of the proposed wage index cap policy.

Comment: MedPAC expressed support for the wage index cap proposal, but recommended that the 5-percent cap also extend to wage index increases of more than 5 percent, such that no geographic area would have its wage index value increase or decrease by more than 5 percent in any given year. In addition, MedPAC recommended that the implementation of the revised relative wage index values (where changes are limited to plus or minus 5 percent) should be done in a budget-neutral manner.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the proposed rule, one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. As we noted in the FY 2023 Hospice proposed rule (87 FR 19447), we believe applying a 5-percent cap on all wage index decreases would support increased predictability about hospice payments for providers, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of hospice payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy would enable hospices to more effectively budget and plan their operations. Rather, we believe it would be more appropriate to allow providers that would experience an increase in their wage index value to receive the full benefit of their increased wage index value.

Comment: A few commenters recommended lowering the threshold percentage of the cap to percentages ranging from 2 percent to 4 percent. In general, these commenters believe that a more gradual approach to lowering the cap would better allow hospices to plan their operations. One commenter stated that lowering the threshold of the wage index cap would protect hospice providers who are already operating with negative operating margins and still experiencing multiple negative consequences due to the COVID pandemic, such has increased costs and loss of staff. Another commenter recommended that CMS finalize the permanent cap on hospice wage index decreases to 2 percent in a non-budget neutral way.

Response: We believe that the 5-percent cap on wage index decreases is an adequate safeguard against any significant payment reductions and that lowering the cap on wage index decreases below 5 percent is not appropriate. We also believe that 5 percent is a reasonable level for the cap because it would more effectively mitigate any significant decreases in a hospice's wage index for future FYs, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Additionally, we believe that a 5-percent cap on wage index decreases in FY 2023 and beyond is sufficient and provides a degree of predictability in payment changes for providers; and it would not be appropriate to implement the cap policy in a non-budget neutral manner. Our longstanding policy is to apply the wage index standardization factors to hospice payments to eliminate the aggregate effect of wage index updates and revisions, such as updates in the underlying hospital wage data as well as other proposed wage index policies, resulting in any wage index changes being budget-neutral in the aggregate. In the FY 2023 hospice proposed rule (87 FR 19448), we stated that we believe that applying a 5-percent cap on all wage index decreases, from the prior year, would have a small overall impact

on the labor market area wage index system. We estimate that applying a 5-percent cap on all wage index decreases, from the prior year, will have a very small effect on the wage index budget standardization factors for FY 2023 and we expect the impact to the wage index budget neutrality factor in future years will continue to be minimal.

Comment: A few commenters requested a temporary transition policy for providers that saw decreases in their FY 2022 wage indexes. Several commenters recommended CMS adopt a transition policy that treats affected hospice providers' FY 2023 wage index as if a 5-percent cap had also been implemented for FY 2022, while other commenters requested that CMS retroactively apply the permanent wage index cap proposal to FY 2022 payments.

Response: We thank commenters for these recommendations. In FY 2021 rulemaking, CMS proposed and finalized the one-year transition policy for FY 2021 only. We have historically implemented 1-year transitions, as discussed in the FY 2006 (70 FR 45137) and FY 2016 (80 FR 47142) final rules, to address CBSA changes due to substantial updates to OMB delineations. Our policy principles with regard to the wage index are to use the most current data and information available. Therefore, we proposed that the FY 2023 Hospice wage index policy would be prospective to mitigate any significant decreases beginning in FY 2023, not retroactively.

As such, we did not calculate or propose the FY 2023 wage index as if the cap was in place for 2022. We note that we received comments on the FY 2022 proposed rule requesting an extension to the one-year transition policy for FY 2021; however, because we did not propose this policy, or the wage index standardization factors that we would have anticipated such a potential policy proposal to require in the FY 2023 proposed rule, we did not propose a policy that treats affected hospice providers' FY 2023 wage index as if a 5-percent cap had also been implemented for FY 2022, or include any data and information that warrant the use of a cap for FY 2022 data in order to calculate the FY 2023 wage index. While such a policy may benefit some providers, it would change the wage index standardization factors, and would impact the FY 2023 payment rates for all providers without allowing them the opportunity to comment.

Final Decision: CMS is finalizing for FY 2023 and subsequent years the application of a permanent 5-percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we are finalizing our policy that a geographic area's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index would not be less than 95 percent of its wage index calculated in the prior FY. We are codifying the permanent cap on wage index decreases in regulation at § 418.306(c).

As previously discussed, we believe this methodology will maintain the hospice wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of hospice payments for providers, and mitigate instability and significant negative impacts to providers resulting from significant changes to the wage index. In section X of this final rule, we estimate the impact to payments for providers in FY 2023 based on this policy. We also note that we will examine the effects of this policy on an ongoing basis in the future in order to assess its appropriateness.

3. FY 2023 Hospice Payment Update Percentage

Section 4441(a) of the BBA (Pub. L. 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the inpatient hospital market basket percentage increase set out under section 1886(b)(3)(B)(iii) of the Act, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the inpatient market basket percentage increase for that FY. In the FY 2022 IPPS final rule CMS finalized the proposal to rebase and revise the IPPS market baskets to reflect a 2018 base year. We refer readers to the FY 2022 IPPS final rule for further information (86 FR 45194 through 45208).

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as ''private nonfarm business total factor productivity.'' However, as mentioned, the data and methods are unchanged. We refer readers to *http://www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* In addition, in the FY 2022 IPPS final rule (86 FR 45214), we noted that beginning with FY 2022, CMS changed the name of this adjustment to refer to it as the ''productivity adjustment'' rather than the ''MFP adjustment''.

In the FY 2023 Hospice Wage Index and Payment Rate Update proposed rule (87 FR 19448), we proposed a hospice market basket increase of 3.1 percent for FY 2023 using the most current estimate of the inpatient hospital market basket (based on IHS Global Inc.'s fourth quarter 2021 forecast with historical data through the third quarter 2021). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the proposed inpatient hospital market basket update for FY 2023 of 3.1 percent was reduced by a productivity adjustment as mandated by the Affordable Care Act (estimated in the proposed rule to be 0.4 percentage point for FY 2023). Therefore, the proposed hospice payment update percentage for FY 2023 was 2.7 percent.

We stated that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, more recent estimates of the

inpatient hospital market basket update and productivity adjustment), we would use such data, if appropriate, to determine the hospice payment update percentage for FY 2023 in the final rule. For this final rule, based on IHS Global Inc.'s (IGI) second quarter 2022 forecast with historical data through the first quarter 2022 of the inpatient hospital market basket update, the market basket percentage increase for FY 2023 is 4.1 percent. The productivity adjustment for FY 2023, based on IGI's second quarter 2022 forecast, is 0.3 percent. Therefore, the hospice payment update percentage for FY 2023, based on more recent data, is 3.8 percent.

We continue to believe it is appropriate to routinely update the hospice payment system so that it reflects the best available data about differences in patient resource use and costs among hospices as required by the statute. Therefore, we proposed to: (1) update hospice payments using the methodology outlined and apply the 2018-based IPPS market basket update for FY 2023 of 4.1 percent, reduced by the statutorily required productivity adjustment of 0.3 percentage point along with the wage index budget neutrality adjustment to update the payment rates; and (2) use the FY 2023 hospice wage index which uses the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index as its basis.

In the FY 2022 Hospice Wage Index final rule (86 FR 42532 through 42539), we rebased and revised the labor shares for RHC, CHC, GIP and IRC using MCR data for freestanding hospices (CMS Form 1984–14, OMB Control Number 0938–0758) from 2018. The current labor portion of the payment rates are: for RHC, 66.0 percent; for CHC, 75.2 percent; for GIP, 63.5 percent; and for IRC, 61.0 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. The non-labor portion of the payment rates are as follows: for RHC, 34.0 percent; for CHC, 24.8 percent; for GIP, 36.5 percent; and for IRC, 39.0 percent.

We received 28 comments on the proposed hospice update percentage of 2.7 percent. A summary of the comments and our responses to those comments are as follows:

Comment: One commenter expressed support for the 2.7 percent payment update and the 2-percentage point reduction for hospices that do not provide quality data.

Response: We thank the commenter for their support of the hospice payment update percentage.

Comment: MedPAC stated that while the commission recognizes that CMS is required by statute to propose an increase to the FY 2023 base rates by 2.7 percent, they recommend no update to the FY 2022 payment rates for FY 2023 (that is, hold the payment rates for FY 2023 at the FY 2022 levels).

Response: We thank the commission for their recommendation; however, we are statutorily required to update the payment rates for FY 2023 and do not have the authority to hold the payment rates to FY 2022 levels. Section 1814(i)(1)(C)(iii) of the Act requires the Secretary, for years subsequent to the first FY in which payment revisions described in paragraph (6)(D) are implemented, to update the payment rates by the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) of the Act for the FY; section 1814(i)(1)(C)(iv)(I) of the Act requires that subsequent to such increase, the payment rates be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Comment: Many commenters expressed concerns about the proposed 2.7 percent payment rate update, especially when the 2 percent sequestration resumes in July 2022. Commenters stated hospice providers have incurred increased costs due to inflation and a health care workforce shortage, which is driving up the cost to hire and retain qualified staff. Several commenters stated hospices have also continued to incur costs to address the COVID–19 PHE, including for personal protective equipment and other infection control efforts. Several commenters noted the increase in gas prices and its impact on hospices, given the preponderance of home-based care delivery.

Several commenters noted that CMS stated that if more recent data became available after the publication of the proposed rule and before the publication of the final rule, it would consider such data to determine the hospice payment update percentage for FY 2023 in the final rule. They encouraged CMS to review the data carefully and exercise its flexibilities to more accurately determine adjustments to the hospice payment rates to account for inflation, ensuring adequate reimbursement.

Other commenters encouraged CMS to finalize a payment rate increase reflective of the current cost of care recommending that CMS pursue all possible administrative options available and provide a higher payment update for FY 2023. One commenter stated that to the extent CMS is restricted by statutory formulas for updating hospice payments, they recommend CMS work with the Congress to effectuate a higher, more sustainable hospice payment update percentage for FY 2023. Several commenters stated that if CMS is considering other alternatives to the hospital rate update that would take into account costs and challenges due to the COVID–19 PHE and inflation, then CMS should consider applying these same updates to the hospice rates. Commenters also requested CMS examine trends relative to IHS Global Inc.'s forecasts to determine whether more recently available data used for the final FY 2023 rule would result in a higher market basket update and determine whether additional updates could be made during the course of FY 2023 to provide additional support to hospice and other providers.

Response: Section 1814(i)(1)(C) of the Act, requires hospice payment rates be updated by the inpatient hospital market basket update and reduced by a productivity adjustment as mandated by the Affordable Care Act.

As described in the FY 2022 IPPS final rule (86 FR 45194 through 45214), the IPPS market basket is a fixed-weight, Laspeyres-type index that measures price changes over time of the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care. It would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the IPPS market basket update would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices), but would not reflect other factors that might increase the level of costs, such as the quantity of labor used.

We agree with the commenters that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. At the time of the FY 2023 hospice proposed rule, based on IHS Global Inc. fourth quarter 2021 forecast with historical data through third quarter 2021, IHS Global Inc. forecasted the 2018-based IPPS market basket update of 3.1 percent for FY 2023 reflecting forecasted compensation price growth of 3.8 percent (by comparison, compensation price growth in the IPPS market basket averaged 2.1 percent over the 2012–2021 time period). In the FY 2023 Hospice proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2023 hospice payment update for the final rule. For this final rule, we now have an updated forecast of the price proxies

underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the United States economy and expected price inflation for FY 2023 for IPPS hospitals. Based on the IHS Global Inc. second quarter 2022 forecast with historical data through first quarter 2022, we are projecting a FY 2023 IPPS market basket update of 4.1 percent (reflecting forecasted compensation price growth of 4.8 percent) and productivity adjustment of 0.3 percentage point. Therefore, for FY 2023 a final hospice payment update of 3.8 percent (4.1 percent less 0.3 percentage point) will be applicable, compared to 2.7 percent as proposed. We note that the final FY 2023 IPPS market basket growth rate of 4.1 percent would be the highest market basket update implemented in an IPPS final rule going back to FY 1998.

Comment: A few commenters requested that CMS consider updating the base year for the hospital IPPS market basket from the current base year of 2018 to a more current base year. The commenter stated that this update will more accurately reflect the cost structure of hospital IPPS during the pandemic for inflationary adjustments to be applied against within the hospice wage index formula. One commenter noted that while they recognize that more recent final data may not yet be available, it should be clear that providers' cost structures have changed since 2018, including changes in operations that have been required as a result of the COVID–19 PHE.

Response: The CMS market baskets are fixed-weight, Laspeyres-type indexes in that they measure ''pure'' price changes only. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured. Changes in quantity or mix of goods and services do eventually get incorporated into the market basket cost weights when it is rebased. Therefore, we rebase the market baskets periodically so that the cost weights reflect more recent purchases of goods and services used by providers to furnish medical care. The IPPS market basket was last rebased in the FY 2022 IPPS final rule using 2018 Medicare cost reports (86 FR 45194 through 45207), the most recent year of complete data available at the time of the rebasing. We did not propose to rebase the IPPS market basket in the FY 2023 IPPS proposed rule. However, we did review the most recent Medicare cost report (MCR) data available for IPPS hospitals submitted as of March 2022, which includes data for 2019 through 2020. The MCR data for 2019 showed little change in the reported cost weights and MCR data for 2020 showed a slight decrease in the compensation cost weight (roughly 1 percentage point) relative to the 2018-based IPPS market basket cost weight. Data through 2021 are incomplete at this time. Based on this preliminary analysis, the impact on the cost weights through 2020 are minimal and it is unclear whether these trends (particularly the compensation cost weight) through 2020 are reflective of sustained shifts in the cost structure for hospitals or whether they were temporary as a result of the COVID–19 PHE. Therefore, we continue to believe it is premature at this time to use more recent MCR data to derive a rebased and revised IPPS market basket. We will continue to monitor these data and any changes to the IPPS market basket will be proposed in future rulemaking.

Final Decision: We are finalizing the hospice payment update percentage of 3.8 percent for FY 2023. Based on IHS Global, Inc.'s more recent forecast of the inpatient hospital market basket update and the productivity adjustment, the hospice payment update percentage for FY 2023 will be 3.8 percent for hospices that submit the required quality data and 1.8 percent (FY 2023 hospice payment update of 3.8 percent minus 2 percentage points) for hospices that do not submit the required data.

4. FY 2023 Hospice Payment Rates

There are four payment categories that are distinguished by the location and intensity of the hospice services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and GIP is to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates: (1) RHC rate for the first 60 days; and (2) RHC rate for days 61 and beyond. In addition, in that final rule, we implemented an SIA payment for RHC when direct patient care is provided by an RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours total) that occurred on the day of service, if certain criteria are met. In order to maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a service intensity add-on budget neutrality factor (SBNF). The SBNF is used to reduce the overall RHC rate in order to ensure that SIA payments are budget-neutral. At the beginning of every FY, SIA utilization is compared to the prior year in order calculate a budget neutrality adjustment.

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments to eliminate the aggregate effect of annual variations in hospital wage data. Typically, the wage index standardization factor is calculated using the most recent, complete hospice claims data available. However, due to the COVID–19 PHE, in the FY 2022 Hospice Wage Index and Payment Rate Update proposed rule we looked at using hospice claims data before the declaration of the COVID–19 PHE (FY 2019) to determine if there were significant differences between utilizing 2019 and 2020 claims data. The difference between using FY 2019 and FY 2020 hospice claims data was minimal. Therefore, in the FY 2022 Hospice Wage Index and Payment Rate Update final rule (86 FR 42543), we stated that we would continue our practice of using the most recent, complete hospice claims data available. For FY 2023 hospice rate setting, we saw minimal differences in using the updated data; therefore, we are continuing our longstanding policy of using the most recent data available. Specifically, we are using FY 2021 claims data with the FY 2023 payment rate updates. In order to calculate the wage index standardization factor, we simulate total payments using FY 2021 hospice utilization claims data with the FY 2022 wage index (pre-floor, pre-reclassified hospital wage index with the hospice floor, without the 5-percent cap on wage index decreases) and FY 2022 payment rates and compare it to our simulation of total payments using the FY 2023 hospice wage index (pre-floor, pre-reclassified hospital wage index with hospice floor, with the 5-percent cap on wage index decreases) and FY 2022 payment rates. By dividing payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the FY 2022 wage index and payment rates for each level

of care by the FY 2023 wage index and FY 2022 payment rates, we obtain a wage index standardization factor for each level of care. The wage index standardization factors for each level of care are shown in the Tables 1 and 2.

The FY 2023 RHC rates are shown in Table 1. The FY 2023 payment rates for CHC, IRC, and GIP are shown in Table 2.

TABLE 1: FY 2023 Hospice RHC Payment Rates

Code	Description	FY 2022 Payment Rates	SIA Budget Neutrality Factor	Wage Index Standardization Factor	FY 2023 Hospice Payment Update	FY 2023 Payment Rates
651	**Routine Home Care (days 1-60)**	$203.40	1.0003	1.0007	1.038	$211.34
651	**Routine Home Care (days 61+)**	$160.74	1.0003	1.0006	1.038	$167.00

TABLE 2: FY 2023 Hospice CHC, IRC, and GIP Payment Rates

Code	Description	FY 2022 Payment Rates	Wage Index Standardization Factor	FY 2023 Hospice Payment Update	FY 2023 Payment Rates
652	**Continuous Home Care Full Rate = 24 hours of care.**	$1,462.52	1.0026	1.038	$1,522.04
655	**Inpatient Respite Care**	$473.75	1.0007	1.038	$492.10
656	**General Inpatient Care**	$1,068.28	1.0017	1.038	$1,110.76

Sections 1814(i)(5)(A) through (C) of the Act require that hospices submit quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index and Rate Update final rule (76 FR 47320 through 47324), we implemented a HQRP as required by those sections. Hospices were required to begin collecting quality data in October 2012 and submit those quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. The FY 2023 rates for hospices that do not submit the required quality data would be updated by the FY 2023 hospice payment update percentage of 3.8 percent minus 2 percentage points. These rates are shown in Tables 3 and 4.

TABLE 3: FY 2023 Hospice RHC Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2022 Payment Rates	SIA Budget Neutrality Factor	Wage Index Standardization Factor	FY 2023 Hospice Payment Update of 3.8% minus 2 percentage points = +1.8%	FY 2023 Payment Rates
651	Routine Home Care (days 1-60)	$203.40	1.0003	1.0007	1.018	$207.27
651	Routine Home Care (days 61+)	$160.74	1.0003	1.0006	1.018	$163.78

TABLE 4: FY 2023 Hospice CHC, IRC, and GIP Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2022 Payment Rates	Wage Index Standardization Factor	FY 2023 Hospice Payment Update of 3.8% minus 2 percentage points = +1.8%	FY 2023 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care.	$1,462.52	1.0026	1.018	$1,492.72
655	Inpatient Respite Care	$473.75	1.0007	1.018	$482.62
656	General Inpatient Care	$1,068.28	1.0017	1.018	$1,089.36

Final Decision: We are finalizing the FY 2023 payment rates in accordance with statutorily mandated requirements.

5. Hospice Cap Amount for FY 2023

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47183), we implemented changes mandated by the IMPACT Act of 2014 (Pub. L. 113–185). Specifically, we stated that for accounting years that end after September 30, 2016 and before October 1, 2025, the hospice cap is updated by the hospice payment update percentage rather than using the CPI–U. Division CC, section 404 of the CAA 2021 extended the accounting years impacted by the adjustment made to the hospice cap calculation until 2030. In the FY 2022 Hospice Wage Index final rule (86 FR 42539), we finalized conforming regulations text changes at § 418.309 to reflect the provisions of the CAA 2021. Therefore, for accounting years that end after September 30, 2016 and before October 1, 2030, the hospice cap amount is updated by the hospice payment update percentage rather than using the CPI–U.

The hospice cap amount for the FY 2023 cap year is $32,486.92, which is equal to the FY 2022 cap amount ($31,297.61) updated by the FY 2023 hospice payment update percentage of 3.8 percent.

We received few comments regarding the hospice cap amount. A summary of these comments and our responses to those comments are as follows:

Comment: MedPAC recommended that the hospice aggregate cap be wage adjusted and reduced by 20 percent. Another commenter recommended several refinements to the cap including: wage adjusting the cap to address wage variation in a budget neutral manner, phasing in the adjustment over multiple years to minimize the potential impact on access to care and to allow the most negatively impacted areas of the country to adjust; and limiting variation in the wage index applicable to the cap (creating a ''floor''

and a ''ceiling'') to protect hospice providers from the significant swings that can accompany wage index changes from year to year, ensuring the cap value remains more consistent. One commenter stated that they would support a cap structure that aligns with hospices taking risk, but that also considers high inflationary factors. This commenter believes that CMS should align payment to account for these factors.

Response: We thank the commenters for their recommendations to improve the hospice cap; however, we are required by law to update the hospice cap amount from the preceding year by the hospice payment update percentage, in accordance with section 1814(i)(2)(B)(ii) of the Act. Therefore, we do not have the statutory authority to reduce the aggregate cap amount nor the statutory authority to wage-adjust the cap.

Final Decision: We are finalizing the update to the hospice cap amount for FY 2023 in accordance with statutorily mandated requirements.

B. Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

The HQRP specifies reporting requirements for the Hospice Item Set (HIS), administrative data, and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. Section 1814(i)(5) of the Act requires the Secretary to establish and maintain a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act was amended by section 407(b) of Division CC, Title IV of the CAA 2021 (Pub. L. 116–260) to change the payment reduction for failing to meet hospice quality reporting requirements from 2 to 4 percentage points. This policy will apply beginning with FY 2024 annual payment update (APU) that is based on CY 2022 quality data. Specifically, the Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and beginning with the FY 2024 APU and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. Since this payment penalty increase to 4 percent is statutorily required and self-implementing, we cannot address comments on this topic.

Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points through FY 2023 or 4 percentage points beginning in FY 2024 could result in the annual market basket update being less than zero percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. A reduction of 2 percentage points through FY 2023 or 4 percentage points beginning in FY 2024 based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the specified year. Typically, about 18 percent of Medicare-certified hospices are found non-compliant with the HQRP reporting requirements and subject to the APU payment reduction for a given fiscal year.

In the FY 2022 Hospice Wage Index and Payment Rate Update final rule (86 FR 42552), we finalized two new measures using claims data: (1) Hospice Visits in the Last Days of Life (HVLDL); and (2) Hospice Care Index (HCI). We also finalized a policy that claims-based measures will use 8 quarters of data in order to report on more hospices. In addition, we removed the seven Hospice Item Set (HIS) Process Measures from the program as individual measures and public reporting because the HIS Comprehensive Assessment Measure (NQF #3235) is sufficient for measuring care at admission without the seven individual process measures. For a detailed discussion of the historical use for measure selection and removal for the HQRP quality measures, we refer readers to the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47142) and the FY 2019 Hospice Wage Index and Rate Update final rule (83 FR 38622). In the FY 2022 Hospice Wage Index and Rate Update final rule (86 FR 42553), we finalized § 418.312(b)(2), which requires hospices to provide administrative data, including claims-based measures, as part of the HQRP requirements for § 418.306(b). In that same final rule, we provided CAHPS Hospice Survey updates. We finalized temporary changes to our public reporting policies based on the March 27, 2020 memorandum [3] and provided another tip sheet, referred to as the *Second Edition HQRP Public Reporting Tip Sheet* on the *HQRP Requirements and Best Practices web page.*

As finalized in the FY 2022 Hospice Wage Index and Payment Rate Update final rule (86 FR 42552), the inaugural display of the two new claims-based quality measures (QMs), the Hospice Visits in Last Days of Life (HVLDL) and the Hospice Care Index (HCI) will be available on the Care Compare/Provider Data Catalogue (PDC) web pages. In the FY 2023 Hospice proposed rule, we did not propose any new quality measures. However, we provide updates on already-adopted measures. Table 5 shows all quality measures finalized in the FY 2022 Hospice Wage Index and Payment Rate Update final rule and in effect for the FY 2023 HQRP.

[3] Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Available at: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

TABLE 5: Quality Measures finalized in the FY 2022 Hospice Wage Index Final Rule and in Effect for FY 2023 for the Hospice Quality Reporting Program

Hospice Quality Reporting Program	
NQF#	**Hospice Item Set**
3235	Hospice and Palliative Care Composite Process Measure—HIS-Comprehensive Assessment Measure at Admission includes: 1. Patients Treated with an Opioid who are Given a Bowel Regimen (NQF #1617) 2. Pain Screening 3. Pain Assessment 4. Dyspnea Treatment 5. Dyspnea Screening 6. Treatment Preferences 7. Beliefs/Values Addressed (if desired by the patient)
Administrative Data, including Claims-based Measures	
Pending NQF endorsement	Hospice Visits in Last Days of Life (HVLDL)
Pending NQF endorsement	Hospice Care Index (HCI) 1. Continuous Home Care (CHC) or General Inpatient (GIP) Provided 2. Gaps in Skilled Nursing Visits 3. Early Live Discharges 4. Late Live Discharges 5. Burdensome Transitions (Type 1) – Live Discharges from Hospice Followed by Hospitalization and Subsequent Hospice Readmission 6. Burdensome Transitions (Type 2) – Live Discharges from Hospice Followed by Hospitalization with the Patient Dying in the Hospital 7. Per-beneficiary Medicare Spending 8. Skilled Nursing Care Minutes per Routine Home Care (RHC) Day 9. Skilled Nursing Minutes on Weekends 10. Visits Near Death
CAHPS Hospice Survey	
2651	CAHPS Hospice Survey 1. Communication with Family 2. Getting timely help 3. Treating patient with respect 4. Emotional and spiritual support 5. Help for pain and symptoms 6. Training family to care for the patient 7. Rating of this hospice 8. Willing to recommend this hospice

2. Hospice Outcomes & Patient Evaluation (HOPE) Update

As finalized in the FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule (84 FR 38484), we are developing a hospice patient assessment instrument identified as HOPE. HOPE would contribute to the patient's plan of care through patient assessments ongoing throughout the hospice stay. HOPE is intended to support the hospice conditions of participation (CoPs), including hospices' quality assessment and performance improvement (QAPI) programs and provide quality data to calculate outcome and other types of quality measures. Our primary objectives for HOPE are to provide quality data for the HQRP requirements through standardized data collection; support survey and certification processes; and provide additional clinical data that could inform future payment refinements.

HOPE would include key items from the HIS and demographics like gender and race. Some HIS items would be modified for inclusion in HOPE to increase specificity. This approach to include key demographic information reflects stakeholder feedback discussed in the FYs 2017 and 2018 Hospice Wage Index and Payment Rate Update final rules (81 FR 52171 and 82 FR 36669, respectively).

HOPE is multidisciplinary: the assessment instrument would be completed by nursing, social work, and spiritual care staff. We are undergoing testing with three distinct disciplinary assessments in beta field testing described in this section. We stated in the FY 2022 Hospice Wage Index and

Payment Update final rule (86 FR 42528) that while the standardized patient assessment data elements for certain post-acute care providers required under the IMPACT Act of 2014 are not applicable to hospices, it would be reasonable to include some of those standardized elements that appropriately and feasibly apply to hospice to the extent permitted by our statutory authority. Some patients may move through the healthcare system to hospice. Therefore, considering tracking key demographic and social risk factor items that apply to hospice could support our goals for continuity of care, overall patient care and well-being, interoperability of electronic health information, and health equity that is also discussed in this rule.

The draft of HOPE has undergone cognitive, pilot, and alpha testing, and is undergoing national beta field testing to establish reliability, validity, and feasibility of the assessment instrument. The purpose of the alpha test was to establish preliminary reliability and validity of the draft assessment items, and feasibility of implementing future requirements for hospices to utilize the HOPE assessment. Specifically, the objectives were to:

- Establish inter-rater reliability (IRR) of the assessment items.
- Demonstrate validity of the assessment items.
- Demonstrate feasibility of completing the assessment and time points during the hospice stay for data collection.

HOPE alpha testing was completed at the end of January 2021. Based on the quantitative data analyses and feedback from assessors in alpha testing, the items generally support the feasibility of collecting the data items. Alpha testing also showed that HOPE exhibited acceptable inter-rater reliability ranging from moderate to very good with few exceptions and demonstrated evidence of convergent validity. We used findings of the alpha test to inform decisions about the next draft of the HOPE assessment, which are being tested in the national beta test that began in late fall 2021 and will continue through 2022.

National beta testing allows us to obtain input from participating hospice teams about the assessment instrument and field testing to refine and support the final draft items and assessment time points for HOPE. It also allows us to estimate the time to complete the HOPE data items. We anticipate proposing HOPE in future rulemaking after testing and analyses are complete.

We continue HOPE development in accordance with the Blueprint for the CMS Measures Management System. HOPE development is grounded in information gathering activities to identify and refine hospice assessment domains and candidate assessment items. We appreciate the industry's and national associations' engagement in providing input through information sharing activities, including listening sessions, expert interviews, key stakeholder interviews, and focus groups to support HOPE development. As CMS proceeds with field testing HOPE, we will continue to engage with stakeholders through sub-regulatory channels. In particular, we will continue to host HQRP Forums to allow hospices and other interested parties to engage with us on the latest updates and ask questions on the development of HOPE and related quality measures. We also have a dedicated email account, *HospiceAssessment@cms.hhs.gov,* for comments about HOPE.

We will use field test results to create a final version of HOPE to propose in future rulemaking for national implementation. We will continue to engage all stakeholders throughout this process that includes a variety of sub-regulatory channels and regular HQRP communication strategies, such as Open Door Forums (ODF), Medicare Learning Network (MLN), *CMS.gov* website announcements, listserv messaging, and other ad hoc publicly announced opportunities. We appreciate the support for HOPE and reiterate our commitment to providing updates and engaging stakeholders through sub-regulatory means. HOPE updates can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HOPE* and engagement opportunities, including those regarding HOPE are at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-QRP-Provider-Engagement-Opportunities.*

We received many comments related to HQRP. A summary of these comments and our responses to those comments as it relates to the HOPE update are as follows:

Comment: Commenters were generally supportive of HOPE and ongoing beta testing. Many commenters asked CMS to release additional information on HOPE, including reports and data, ahead of the official proposal to allow time for education, programming, and implementation of HOPE. Specifically, commenters asked for information regarding the timeline for HOPE implementation. There were numerous suggestions that HOPE could include health equity and social determinants of health (SDOH) data points, including those to support a structural health equity measure and assist hospices in assessing their own progress on health equity goals. One comment suggested HOPE as an opportunity to collect uniform self-reported data to support a future health equity structural measure.

A few comments raised concerns about the potential additional regulatory burden of HOPE, such as duplicative documentation. Another comment suggested HOPE leverage certified health IT capabilities to reduce administrative burden. Some comments noted concerns about conducting beta testing during the COVID–19 pandemic, stating that staffing concerns have exacerbated the administrative burden of HOPE beta testing. There was one comment suggesting the inclusion of occupational therapy practitioners among the providers who can complete HOPE assessments.

Response: We appreciate all stakeholders' input regarding HOPE development, and will take these comments into consideration for future rulemaking. We are committed to developing and implementing HOPE with a minimum burden to stakeholders. Additional information about HOPE will be presented to the public via sub-regulatory means, such as ODFs, Hospice Quality Reporting Program Forums, our HQRP web page, and other appropriate communications. We will propose HOPE in future rulemaking.

3. Update on Future Quality Measure (QM) Development

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we provided updates related to CMS's process for identifying high priority areas of quality measurement and improvement and for developing quality measures that address those priorities. Information on the current HQRP quality measures can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.* In this final rule, we provide updates for hospice quality measure concepts based on future use of HOPE and administrative data. In section III.B.6, we summarize the public comments from hospices on the Request for Information (RFI) related to their health equity initiatives and a structural composite measure concept to inform future measure development.

To support new measure development, our contractor convened two technical expert panel (TEP)

meetings in 2021. The TEP considered HOPE-based process measures that may be proposed with HOPE in future rulemaking. The TEP meetings in 2021 included HOPE-based process measures intended to: (1) evaluate the rate at which hospices' use specific processes of care; (2) assist in reducing variation in care delivery; and (3) determine hospices' compliance with practices that are expected to improve outcomes. The TEP also considered potential areas for future quality measure development. We refer readers to the ''2021 Technical Expert Panel Meetings: Hospice Quality Reporting Program Summary Report'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-QRP-Provider-Engagement-Opportunities*.

As stated in the FY 2022 Hospice Wage Index and Rate Update final rule (86 FR 42528), We continue to consider developing hybrid quality measures that could be calculated from multiple data sources: for example, claims, assessments (HOPE), or other data sources. Hybrid quality measures allow for a more comprehensive set of information about care processes and outcomes than can be calculated using claims data alone. As described in the ''2021 Technical Expert Panel Meetings: Hospice Quality Reporting Program Summary Report,'' the TEP discussed hybrid concepts such as hospitalizations during a hospice election and patterns of live discharge using claims data and HOPE data elements.

We received several comments regarding the update on future QM development. A summary of these comments and our responses to those comments are as follows:

Comment: Several commenters suggested CMS develop measures to monitor hospice telehealth services and to add telehealth to claims. Some commenters indicated that existing measures, such as the claims-based HVLDL should be modified to recognize telehealth.

Other commenters suggested that CMS develop or revise quality measures to better reflect how hospices meet patient care goals. These suggestions included new quality measures for advance care planning and patient-reported measures related to how much patients felt understood and whether patients received the pain help they wanted. Related to these care goals and for future quality measure consideration, commenters seek to recognize visits by the full interdisciplinary care team, add spiritual care to claims, and consider occupational therapy and/or include it in the NQF #3235, the HIS Comprehensive Assessment Measure.

Commenters also recommended changes to the existing HVLDL measure, such as revising the specifications to recognize more hospice disciplines, including telehealth visits, or changing the timeframe the measure reflects.

In addition, commenters suggested changes to the existing HCI measure, such as differentiating when patients refuse provider visits from when providers fail to offer visits, or changing the timeframe of the ''Visits Near Death'' indicator.

Commenters made suggestions regarding how future QMs should be designed. These suggestions included considerations for hybrid measures and requests for more clarity on how CMS determines if proposed measures address quality of care. Other commenters emphasized the importance of minimizing the administrative burden of new quality measure implementation and data collection.

Response: We appreciate the input regarding quality measure development, and will take these comments into consideration for future QM development initiatives. We are committed to the Meaningful Measures Initiative (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*) and Measures Management System Blueprint (*https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*) that informs and guides quality measure development priorities and processes.

4. Updates to the CAHPS Hospice Survey Participation Requirements for the FY 2023 APU and Subsequent Years

a. Background and Description of the CAHPS Hospice Survey

The CAHPS Hospice Survey is a component of the CMS HQRP, which is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. We refer readers who may want more information about the development of the survey, originally called the Hospice Experience of Care Survey to see our discussions of the survey in the FY 2015 Hospice Wage Index final rule (79 FR 50452, 50491) and the FY 2014 Hospice Wage Index final rule (78 FR 48234, 48261).).

b. Overview of the ''CAHPS Hospice Survey Measures''

The CAHPS Hospice Survey measures were re-endorsed by NQF on November 20, 2020. The re-endorsement can be found on the NQF website at: *https://www.qualityforum.org/Measures_Reports_Tools.aspx.* The survey received its initial NQF endorsement on October 26, 2016 (NQF #2651). We adopted 8 survey-based measures for the CY 2018 data collection period and for subsequent years. These eight measures are publicly reported on a designated CMS website, Care Compare, *https://www.medicare.gov/care-compare/.*

c. CAHPS Hospice Survey Mode Experiment

CMS recently conducted a mode experiment with the goal of testing the effects of adding a web-based mode to the CAHPS Hospice Survey. We are examining the impact of a web-based mode on survey response rates and scores. The survey currently has three approved modes without any web component (mail, telephone, and mail with telephone follow-up). In addition, the test will allow for examination of the effects of a shortened survey (that is, removing existing survey items) on response rate and scores; assessment of the measure properties of a limited number of supplemental survey items suggested by stakeholders; and calculation of item-level mode adjustments for the shortened survey in the currently-approved modes of CAHPS Hospice Survey administration, as well as the proposed new web-based mode.

The mode experiment design applied all of the existing CAHPS Hospice Survey eligibility criteria, and sampled patients/caregivers across five arms. The first arm tested a new web-mail mode, in which invitations to the web survey were sent by email to those with email addresses. The email was personalized to the respondent and included a link to the web version of the survey, which can be completed on either a computer or a mobile device such as a smartphone or tablet. If the respondent did not complete the web survey after one week, or did not have a valid email address in which to send an email, up to two surveys were sent by mail. This arm used a shortened version of the CAHPS Hospice Survey.

In the next three arms, the shortened version of the CAHPS Hospice Survey instrument was administered in the three currently-approved modes: mail only; telephone-only; and mixed mode (mail with telephone follow up). The fifth arm, in which the current survey instrument was administered via mail only served as a comparison for all other arms. Across all arms, half of sampled caregivers received a pre-notification letter to examine the effects of such a letter on response rates.

Overall (across the five arms), CMS sampled 15,000 eligible caregivers from around 50 hospices over a six- to seven-month period. Caregivers were randomized within each hospice to one of the five arms.

We continue to analyze the results of the mode experiment and will keep stakeholders informed on any plans for changes to the survey content or administration options through our regular stakeholder communication channels. In this final rule, there are no changes to the administration procedures or content for the CAHPS Hospice Survey. Any changes to the CAHPS Hospice Survey will be proposed in future rulemaking.

We received several comments regarding the CAHPS Hospice Survey Mode Experiment. A summary of these comments and our responses to those comments are as follows:

Comment: Most commenters support the development and testing of a web-based mode and a shortened version of the CAHPS Hospice Survey.

Response: We appreciate the support of a web-based mode of survey administration and shorter CAHPS Hospice Survey instrument. Currently, CMS is completing analyses of data collected through a field test that included the web-based mode of survey administration and revisions to the survey. If and when a web-based mode is made available as one of the approved modes of CAHPS Hospice Survey administration, hospices would continue to have the option to choose among all approved modes (that is, web-based mode would not be required). Prior to introducing a revised survey instrument and/or new approved mode of administration, CMS will release detailed information regarding proposed changes to survey instrument content, survey administration protocols, and data adjustment procedures needed to promote fair comparisons between hospices selecting different modes of survey administration.

Comment: Some commenters stated that CMS should examine the CAHPS Hospice Survey to ensure questions are appropriate for ethnically diverse families and provide information that can be used to address health equity.

Response: We will continue to use data from hospices participating in the CAHPS Hospice Survey to assess how care experiences vary for subpopulations across hospices. In 2021, CMS conducted an experiment of a revised version of the CAHPS Hospice Survey that included new survey questions designed to assess cultural sensitivity of care and identify disparities in care by race and ethnicity. We will share information about the results of this test as it becomes available.

Comment: Some commenters stated that CMS should compare response rates to the CAHPS Hospice Survey and other CAHPS surveys for non-English speaking individuals to assess whether these rates vary from English-speaking individuals.

Response: We thank commenters for this feedback and will take this suggestion into consideration. Data has shown for other CAHPS surveys that the likelihood of responding to survey differs by race/ethnicity and mode. We encourage hospices to consider their patient/caregiver population and work with their survey vendor to determine the best mode of data collection.

Comment: One commenter stated that the CAHPS Hospice Survey is not an accurate reflection of care received since the primary caregiver completes the survey.

Response: The Hospice CAHPS Survey is completed by the primary caregiver out of respect for the patient receiving end of life care. We do not feel it would be appropriate to have hospice patients fill out a survey about the care they are receiving at the very end of their life.

d. Data Sources

In the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38484), we finalized the participation requirements for the CAHPS Hospice Survey. To meet the CAHPS Hospice Survey requirements for the HQRP, hospice facilities must contract with a CMS-approved vendor to collect survey data for eligible patients on a monthly basis and report that data to CMS on the hospice's behalf by the quarterly deadlines established for each data collection period.

e. Public Reporting of CAHPS Hospice Survey Results

We began public reporting of the results of the CAHPS Hospice Survey on Hospice Compare as of February 2018. Before the COVID–19 PHE, we reported the most recent 8 quarters of data on the basis of a rolling average, with the most recent quarter of data being added and the oldest quarter of data removed from the averages for each data refresh. As finalized in the FY 2022 Hospice Wage Index and Payment Rule Update (86 FR 42528), we are not reporting Q1 2020 and Q2 2020 data due to the COVID–19 PHE. Therefore, we have publicly reported the most recently available 8 quarters of CAHPS data that excluded Q1 2020 and Q2 2020 data. These data were publicly reported starting with the February 2022 refresh and will continue through the May 2023 refresh on Care Compare. The Second Edition HQRP Public Reporting Tip Sheet dated Dec. 2021 on the *HQRP Requirements and Best Practices web page* summarizes CMS' approach to the HQRP as public reporting has resumed in February 2022. It also explains the HQRP public reporting changes associated with the FY 2022 Hospice Wage Index and Payment Rule Update final rule and provides a summary of the data refreshes.

f. Volume-Based Exemption for CAHPS Hospice Survey Data Collection and Reporting Requirements

In the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38526), we finalized a policy making a volume-based exemption for CAHPS Hospice Survey Data Collection and Reporting requirements for FY 2021 and every year thereafter.

In this final rule, there will be no changes to this exemption. The exemption request form is available on the official CAHPS Hospice Survey website: *http://www.hospiceCAHPSsurvey.org.* Hospices that intend to claim the size exemption are required to submit to CMS their completed exemption request form by December 31, of the data collection year.

Hospices that served a total of fewer than 50 survey-eligible decedent/caregiver pairs in the year before the data collection year are eligible to apply for the size exemption. Hospices may apply for a size exemption by submitting the size exemption request form. The size exemption is only valid for the year on the size exemption request form. If the hospice remains eligible for the size exemption, the hospice must complete the size exemption request form for every applicable FY APU period, as shown in Table 6.

TABLE 6: Size Exemption Key Dates FY 2023 Through FY 2026

Fiscal year	Data collection year	Reference year	Size exemption form submission deadline
FY 2023	CY 2021	CY 2020	December 31, 2021
FY 2024	CY 2022	CY 2021	December 31, 2022
FY 2025	CY 2023	CY 2022	December 31, 2023
FY 2026	CY 2024	CY 2023	December 31, 2024

g. Newness Exemption for CAHPS Hospice Survey Data Collection and Public Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria as stated in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52181). In the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38642), we continued the newness exemption for FY 2023, and all subsequent years. We encourage hospices to keep the letter they receive providing them with their CMS Certification Number (CCN). The letter can be used to show when you received your number.

h. Survey Participation Requirements

We previously finalized survey participation requirements for FY 2022 through FY 2025 as stated in the FY 2018 and FY 2019 Hospice Wage Index and Payment Rate Update final rules (82 FR 36670 and 83 FR 38642 through 38643). We also continued those requirements in all subsequent years (84 FR 38526). Table 7 restates the data submission dates for FY 2023 through FY 2025.

TABLE 7: CAHPS Hospice Survey Data Submission Dates for the APU in FY 2023, FY 2024, and FY 2025

Sample months (month of death)*	CAHPS Quarterly Data Submission Deadlines**
FY 2023 APU	
CY January-March 2021 (Quarter 1)	August 11, 2021
CY April-June 2021 (Quarter 2)	November 10, 2021
CY July-September 2021 (Quarter 3)	February 9, 2022
CY October-December 2021 (Quarter 4)	May 11, 2022
FY 2024 APU	
CY January-March 2022 (Quarter 1)	August 10, 2022
CY April-June 2022 (Quarter 2)	November 9, 2022
CY July-September 2022 (Quarter 3)	February 8, 2023
CY October-December 2022 (Quarter 4)	May 10, 2023
FY 2025 APU	
CY January-March 2023 (Quarter 1)	August 9, 2023
CY April-June 2023 (Quarter 2)	November 8, 2023
CY July-September 2023 (Quarter 3)	February 14, 2024
CY October-December 2023 (Quarter 4)	May 8, 2024

* Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).

** Data submission deadlines are the second Wednesday of the submission months, which are the months August, November, February, and May.

For further information about the CAHPS Hospice Survey, we encourage hospices and other entities to visit: *https://www.hospiceCAHPSsurvey.org.* For direct questions, contact the CAHPS Hospice Survey Team at *hospicecahpssurvey@hsag.com* or call 1 (844) 472–4621.

i. CAHPS Hospice Survey Star Ratings

We previously finalized a policy requiring us to display Hospice CAHPS Survey Star Ratings no sooner than FY 2022 as stated in the FY 2022 Hospice Wage Index and Payment Rule Update rule (86 FR 42528). Star Ratings will be publicly reported on Care Compare on Medicare.gov beginning with the August 2022 refresh. This start date allowed CMS to conduct a dry run of the Star Ratings with reporting to hospices via preview reports. Hospices first saw their Star Ratings in their preview reports during the November 2021 and March 2022 preview periods for the February 2022 and May 2022 updates of Care Compare on *Medicare.gov*. However, the CAHPS Hospice Survey Star Ratings will not be publicly reported in February or May 2022. The reporting period for the dry run covers data from Q4 2018 through Q4 2019 and Q3 2020 through Q1 2021. Detailed information about the calculation and display of Hospice CAHPS Survey Star Ratings can be found on the official CAHPS Hospice Survey website: *http://www.hospiceCAHPSsurvey.org.* There are no changes to the Hospice CAHPS Survey Star Ratings for FY 2023.

We received several comments regarding the CAHPS Survey Star Ratings. A summary of these comments and our responses to those comments are as follows:

Comment: Some commenters expressed concerns that Star Ratings will only include data from the CAHPS Hospice Survey and therefore will not provide consumers with all the relevant information to decide on selecting a hospice.

Response: Star Ratings using CAHPS Hospice Survey data is an initial step CMS is taking to provide consumers with an easy to understand method for comparing hospices. We will take the feedback to include other data sources into consideration as enhancements are made over time.

Comment: A handful of commenters raised concern that low survey response rates will prevent hospices from being assigned a Star Rating and this could result in fewer hospices having Star Ratings. Several commenters stated that it is not clear how a consumer will perceive a hospice that is not assigned a Star Ratings.

Response: CMS recently tested a web mode and shortened questionnaire with the goal of improving response rates. We are analyzing the data for potential future changes to the Hospice CAHPS Survey. For the August 2022 reporting period, most hospices with publicly reported CAHPS Hospice Survey measure scores (68 percent) met the threshold of 75 completed surveys and were assigned a Star Rating. The vast majority of 2020 Medicare decedents (approximately nine out of ten) received care from hospices that received a Star Rating in August 2022. CMS presents footnotes and other documentation on the Care Compare website to clearly indicate why hospices with smaller numbers of completed surveys do not have Star Ratings.

Comment: A commenter suggested that Star Ratings be calculated based on absolute rather than relative performance.

Response: Similar to other CMS CAHPS Star Ratings, CMS finalized that the cut-point methodology used to determine CAHPS Hospice Survey stars use statistical clustering procedures that minimize the score differences within a star category and maximize the differences across star categories. This ensures that star assignments clearly differentiate performance across groups of hospices. Such comparative Star Ratings help consumers identify high and low performing hospices. Statistical clustering also allows cut points to adjust for unanticipated changes in performance within the industry. Setting absolute cut points has multiple issues, including variation in industry performance across measures, external or structural factors can lead to substantial changes from period to period rather than steady, slow year-over-year improvement, and diminished incentive to improve when a hospice knows they have reached a certain pre-established performance threshold.

Comment: A couple of commenters shared concerns that the time period of data used to calculate quality measures, including Star Ratings for the CAHPS Hospice Survey, includes data up to 3 years old which undermines the usefulness of the information being publicly reported.

Response: Rolling up eight quarters of data instead of four ensures that measure scores are available for many more hospices, which improves the usefulness of the Compare web tools for hospice consumers. The eight-quarter approach does not result in a delay of when data becomes available (since the most recent quarters of data are included in the rolled-up score), but it does ensure more accurate measurement. The decision to use eight quarters of rolling data for hospices reflects sample size issues that are specific to hospice organizations, which differ in size and other dimensions from other types of entities, such as hospitals and MA contracts, for which CMS publicly reports scores and Star Ratings.

5. Form, Manner, and Timing of Quality Data Submission

a. Statutory Penalty for Failure To Report

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act was amended by the CAA 2021 and the payment reduction for failing to meet hospice quality reporting requirements is increased from 2 percent to 4 percent beginning with FY 2024. The Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and then beginning in FY 2024 and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that fiscal year. Last year, we revised our rule at § 418.306(b)(2) in accordance with this statutory change (86 FR 42605).

b. Compliance

HQRP Compliance requires understanding three timeframes for both HIS and CAHPS: (1) The relevant Reporting Year, payment FY and the Reference Year. The ''Reporting Year'' (HIS)/''Data Collection Year'' (CAHPS). This timeframe is based on the calendar year. It is the same CY for both HIS and CAHPS. If the CAHPS Data Collection year is CY 2023, then the HIS reporting year is also CY 2023; (2) The APU is subsequently applied to FY payments based on compliance in the corresponding Reporting Year/Data Collection Year; and (3) For the CAHPS Hospice Survey, the Reference Year is the CY prior to the Data Collection Year. The Reference Year applies to hospices submitting a size exemption from the CAHPS survey (there is no similar exemption for HIS). For example, for the CY 2023 data collection year, the Reference Year, is CY 2022. This means providers seeking a size exemption for CAHPS in CY 2023 will base it on their hospice size in CY 2022. Submission requirements are codified in § 418.312.

For every CY all Medicare-certified hospices are required to submit HIS and CAHPS data according to the requirements in § 418.312. Table 8 summarizes the three timeframes. It illustrates how the CY interacts with the FY payments, covering the CY 2021 through CY 2024 data collection periods and the corresponding APU application from FY 2023 through FY 2026.

TABLE 8: HQRP Reporting Requirements and Corresponding Annual Payment Updates

Reporting Year for HIS and Data Collection Year for CAHPS data (Calendar year)	Annual Payment Update Impacts Payments for the FY	Reference Year for CAHPS Size Exemption (CAHPS only)
CY 2021	FY 2023 APU	CY 2020
CY 2022	FY 2024 APU*	CY 2021
CY 2023	FY 2025 APU	CY 2022
CY 2024	FY 2026 APU	CY 2023

* Beginning in FY 2024 and all subsequent years, the payment penalty is 4 percent. Prior to FY 2024, the payment penalty is 2 percent.

As illustrated in Table 8, CY 2021 data submissions compliance impacts the FY 2023 APU. CY 2022 data submissions compliance impacts the FY 2024 APU. CY 2023 data submissions compliance impacts FY 2025 APU. This CY data submission impacting FY APU pattern follows for subsequent years.

c. Submission Data and Requirements

As finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142, 47192), hospices' compliance with HIS requirements beginning with the FY 2020 APU determination (that is, based on HIS–Admission and Discharge records submitted in CY 2018) are based on a timeliness threshold of 90 percent. This means CMS requires that hospices submit 90 percent of all required HIS records within 30-days of the event (that is, patient's admission or discharge). The 90-percent threshold is hereafter referred to as the timeliness compliance threshold. Ninety percent of all required HIS records must be submitted and accepted within the 30-day submission deadline to avoid the statutorily-mandated payment penalty. Hospice compliance with claims data requirements is based on administrative data collection. Since Medicare claims data are already collected from claims, hospices are considered 100 percent compliant with the submission of these data for the HQRP. There is no additional submission requirement for administrative data.

To comply with CMS' quality reporting requirements for CAHPS, hospices are required to collect data monthly using the CAHPS Hospice Survey. Hospices comply by utilizing a CMS-approved third-party vendor. Approved Hospice CAHPS vendors must successfully submit data on the hospice's behalf to the CAHPS Hospice Survey Data Center. A list of the approved vendors can be found on the CAHPS Hospice Survey website: *www.hospicecahpssurvey.org.* Table 9. HQRP Compliance Checklist illustrates the APU and timeliness threshold requirements.

TABLE 9: HQRP Compliance Checklist

Annual Payment Update	HIS	CAHPS
FY 2023	Submit at least 90 percent of all HIS records within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/21 – 12/31/21.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2021 – 12/31/2021
FY 2024	Submit at least 90 percent of all HIS records or its successor instrument within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/22 – 12/31/22.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2022 – 12/31/2022
FY 2025	Submit at least 90 percent of all HIS records or its successor instrument within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/23 – 12/31/23.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2023 – 12/31/2023

Note: The data source for the claims-based measures will be Medicare claims data that are already collected and submitted to CMS. There is no additional submission requirement for administrative data (Medicare claims), and hospices with claims data are 100-percent compliant with this requirement.

Most hospices that fail to meet HQRP requirements do so because they miss the 90 percent threshold. We offer many training and education opportunities through our website, which are available 24/7, 365 days per year, to

enable hospice staff to learn at the pace and time of their choice. We want hospices to be successful with meeting the HQRP requirements. We encourage hospices to use the website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Reporting-Training-Training-and-Education-Library.* For more information about HQRP Requirements, we refer readers to visit the frequently-updated HQRP website and especially the Best Practice, Education and Training Library, and Help Desk web pages at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting.* We also encourage readers to visit the HQRP web page and sign-up for the Hospice Quality ListServ to stay informed about HQRP.

6. Request for Information Related to the HQRP Health Equity Initiative

CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive. CMS' goals are in line with Executive Order 13985, on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which can be found at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

Belonging to an underserved community is often associated with worse health outcomes.[4] [5] [6] [7] [8] [9] [10] [11] Such disparities in health outcomes are the result of multiple factors. Although not the sole determinants, poor access to care and provision of lower quality health care are important contributors to health disparities notable for CMS programs. Health inequities persist in hospice and palliative care, where Black and Hispanic populations are less likely to utilize care and over 80 percent of patients are White.[12] [13] [14] [15] After hospice admission, racial and ethnic disparities appear to impact quality of care and health outcomes.[16] Black patients may receive fewer supportive care medications despite higher symptom burdens, experience care less consistent with their expressed preferences, and encounter worse end-of-life communication.[17] [18] [19] [20] [21] In response to a survey regarding these disparities, 70 percent of home health organizations, including 22 percent that are hospices, indicated they would increase the resources dedicated to diversity, equity, and inclusion starting in 2021.[22] One important strategy for addressing these disparities is improving data collection to allow for better measurement and reporting on equity across our programs and policies.[23] [24]

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling beneficiaries to make more informed decisions, and promoting provider accountability for health care disparities.[25] [26] CMS is committed to closing the equity gap in CMS quality programs. As discussed in the RFI from the FY 2022 Hospice Wage Index and Rate Update proposed rule (86 FR 19700), we are focused at making information on the quality of health care providers and services, including disparities, more transparent.

In the FY 2022 Hospice Wage Index and Rate Update final rule, we received comments supportive of gathering standardized patient assessment data elements and additional SDOH data to improve health equity. In parallel, commenters advocated for education efforts for beneficiaries, providers, and stakeholders on the benefits of collecting and reporting demographic and social risk factor data. We received many comments about the use of standardized patient assessment data elements in the hospice setting to assess health equity and SDOH, some of which raised concerns around whether such use may have unintended consequences. Many commenters noted that hospice patients have different goals of care than non-hospice patients, which does not align with standardized

[4] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[5] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[6] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[7] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[8] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[9] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[10] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[11] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. medRxiv. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[12] Addressing Disparities in Hospice & Palliative Care. Nalley, Catlin. Oncology Times: March 20, 2021—Volume 43—Issue 6—p 1,10doi: 10.1097/01.COT.0000741732.73529.bb.

[13] *https://journalofethics.ama-assn.org/article/racial-disparities-hospice-moving-analysis-intervention/2006-09.*

[14] Capital Caring, Seasons Execs: Improving Hospice Diversity Starts from the Inside Out. 11/17/21. Holly Vossel. Capital Caring, Seasons Execs: Improving Hospice Diversity Starts from the Inside Out—Hospice & Palliative Care Network of Maryland *https://hospicenews.com/2021/11/17/capital-caring-seasons-execs-improving-hospice-diversity-starts-from-the-inside-out/.*

[15] Disparities in Palliative and Hospice Care and Completion of Advance Care Planning and Directives Among Non-Hispanic Blacks: A Scoping Review of Recent Literature (*nih.gov*).

[16] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3822363/.*

[17] Naming the Problem: A Structural Racism Framework to Examine Disparities in Palliative Care—ScienceDirect.

[18] Johnson KS. Racial and ethnic disparities in palliative care. J Palliat Med 2013;16:1329–1334.

[19] Elk R, Felder TM, Cayir E, Samuel CA. Social inequalities in palliative care for cancer patients in the United States: a structured review. Semin Oncol Nurs 2018;34:303–315.

[20] Elliott AM, Alexander SC, Mescher CA, Mohan D, Bar-nato AE. Differences in physicians' verbal and nonverbal communication with black and white patients at the end of life. J Pain Symptom Manage 2016;51:1–8.

[21] Johnson RL, Roter D, Powe NR, Cooper LA. Patient race/ethnicity and quality of patient-physician communication during medical visits. Am J Public Health 2004;94:2084–2090.

[22] Capital Caring, Seasons Execs: Improving Hospice Diversity Starts from the Inside Out. 11/17/21. Holly Vossel. Capital Caring, Seasons Execs: Improving Hospice Diversity Starts from the Inside Out—Hospice & Palliative Care Network of Maryland *https://hospicenews.com/2021/11/17/capital-caring-seasons-execs-improving-hospice-diversity-starts-from-the-inside-out/.*

[23] *https://hospicenews.com/2021/05/27/hospice-providers-leverage-data-to-reach-the-underserved/.*

[24] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3822363/.*

[25] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[26] Report to Congress: Improving Medicare PostAcute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

data elements for patient assessment. Commenters encouraged CMS to only utilize certain aspects of standardized data elements for patient assessment (specifically, Z-codes 55–65) in collecting health equity data. We refer the readers to review the summary of public comments received in the FY 2022 Hospice Wage Index and Rate Update final rule (86 FR 42528).

We will continue to take all comments and suggestions into account as we work to develop policies on this important topic. We appreciate hospices and national organizations sharing their support and commitment to addressing health disparities and offering meaningful comments for consideration in the FY 2022 Hospice Wage Index and Rate Update final rule (86 FR 42528). Given the value of the comments thus far and the ongoing development of activities to improve health equity, we solicited public comment in the proposed rule on the following questions:

- What efforts does your hospice employ to recruit staff, volunteers, and board members from diverse populations to represent and serve underserved populations?
- How does your hospice attempt to bridge any cultural gaps between your personnel and beneficiaries/clients?
- How does your hospice measure whether this has an impact on health equity?
- How does your hospice currently identify barriers to access in your community or service area?
- What are barriers to collecting data related to disparities, social determinants of health, and equity?
- What steps does your hospice take to address these barriers?
- How does your hospice collect self-reported data such as race/ethnicity, veteran status, socioeconomic status, housing, food security, access to interpreter services, caregiving status, and marital status and use this to inform its health equity initiatives?
- How is your hospice using qualitative data collection and analysis methods to measure the impact of its health equity initiatives?

We received several comments in response to our request for information on the HQRP Health Equity initiative. A summary of these comments and our responses to those comments are as follows:

Comment: Many commenters supported CMS's efforts to create health equity measures. However, commenters wanted more clarity on CMS's plans for health equity measures and what measurement criteria CMS would consider applying to hospices. Comments suggested that CMS should encourage all health care providers and organizations across the continuum of care to collect and stratify patient and caregiver data based on key variables of inequities in patient care for all types of measures.

Comment: Commenters reiterated and acknowledged health disparities in hospice care and were broadly supportive of CMS' efforts to advance health equity and generally expressed appreciation for the opportunity to partner with CMS to address disparities in hospice settings. Many shared their organization's efforts to promote health equity, including staff training and hiring. Despite the overall appreciation, commenters noted that there is great variation in organizational readiness to develop and implement health equity initiatives; for example, hospice providers serving smaller rural communities may not be as far along in integrating health equity activities as larger providers associated with robust hospital systems. Similarly, other comments noted that, to varying degrees, providers may experience the following challenges in implementing a health equity framework and respective quality improvement activities: financial limitations, data collection burden, and workforce shortages. In light of these considerations, commenters requested CMS support in the form of financial and other resources (for example, trainings), ample time for hospices to develop and implement activities to improve health equity, and the use of incentive-based rather than punitive measures to promote reporting. One commenter recommended stratifying the volume and detail of data collected based on the size, independence, and geographic profile of a given hospice. Some suggested convening a Technical Expert Panel (TEP) to inform the development of health equity measures until after HOPE becomes available.

Several commenters highlighted the need for more sociodemographic and social determinants of health (SDOH) data to effectively evaluate health equity in hospice settings. Commenters suggested efforts to standardize the sociodemographic and SDOH data collected across provider settings and across third party vendors (for example, EMRs) and other tools. There was some support for the stratification of confidential data reports by sociodemographic factors. Multiple commenters also recommended incorporating SDOH items into HOPE and delaying public reporting of a health equity measure until HOPE is available.

Comment: Commenters stated that some hospice providers have made progress in recruiting and employing diverse staff to better represent historically underserved populations. Successful strategies have included job marketing and community outreach, educational efforts and partnering with colleges and universities, developing partnerships with groups and associations to promote employment and leadership opportunities, development of diversity, equity, and inclusion (DEI) recruitment teams,[27] sign on bonuses for certain qualifications (for example, bilingual), and scholarships for staff who are members of disproportionately affected populations. Several commenters highlighted the wide variation across hospices with regards to resources and progress made in diversity of staff and leadership and stated that smaller organizations may need additional resources and support to implement recruitment and retention efforts. Other commenters stated that a limited pool of applicants due to workforce shortages is a major challenge across all organizations. One commenter stated that hospice workforce diversity is not necessarily reflective of the diversity in the underlying community and that this is a broader issue which will need to be addressed through coordinated efforts, such as, to recruit more diverse student populations in healthcare and social work programs. Approaches to bridge cultural gaps between personnel and beneficiaries include community outreach and partnerships, DEI training for staff and leadership, DEI organizational assessments, centering equity in organizational mission, values, and goals, and expansion of linguistic capacities.

Comment: Several commenters responded to CMS's request for information about barriers that might prevent community members from seeking hospice care. Commenters reported that strategies to identify and address barriers include training staff, building partnerships, employing community liaisons to work with patients and caretakers, including social determinant of health (SDOH) information in social work assessments and workplans (for example, housing and food insecurity), using toolkits and resources freely available to the public on websites, including national hospice organizations' websites, and working

[27] Diversity recruiting is the practice of hiring candidates using a process that is free from bias for or against any individual or group of candidates. Diverse teams help companies to be more innovative, be more creative, and achieve better results. *https://www.dictionary.com/*.

with EMR vendors to better collect sociodemographic information.

Comment: Many commenters cited barriers to collecting data related to disparities, social determinants of health, and equity. Those barriers included a lack of uniformity and interoperability across EMRs and other tools, lack of standard definitions for sociodemographic and SDOH variables, limited communication channels for administering CAHPS and other data collection instruments, patient mistrust in providing these data, and the administrative burden of data collection.

Commenters provided recommendations to address these barriers such as the standardization of sociodemographic and SDOH data collected across systems, the use of a universal database, and the inclusion of new codes that measure patients' SDOH needs (Z codes) into hospice claims.

Comment: Commenters reported variation in how self-reported data to inform health equity are collected across hospice providers; some collect these data at referral or admissions, while others collect during social work or psychosocial assessments. Some providers are not yet collecting these data and request additional guidance. Although certain sociodemographic or social determinant of health (SDOH) data points are collected through EMR fields, commenters identified issues related to the use of these data. The issues include lack of industry standards noted by several commenters in definitions for these variables and the limits of the EMR system in how the data is stored that impacts the ability to share the data. For example, one commenter described limits with sharing the data because some self-reported variables (for example, race/ethnicity) are collected in parts of the EMR that cannot be easily shared while other variables (for example, need for interpreter services and food insecurity) are collected through other parts of the EMR system and can be shared with partner organizations for referrals and other purposes. Another commenter stated that staff at an organization can use different versions of an EMR, which results in inconsistencies in data.

Many commenters expressed a need for guidance on how to collect health equity related data (for example, sociodemographic and SDOH data points) and how to effectively use them to assess health equity impacts. Commenters indicated a strong need to identify effective methods for collecting sociodemographic and SDOH data among hospice providers. Specifically, several commenters recommended the inclusion of languages other than English (for example, need for bilingual services), whether culture was respected, sexual orientation and gender identity, expanded racial/ethnic categories to capture more detailed information, socioeconomic status, food security, community deprivation level, and caregiving status information. Suggested tools for collecting some of these data points included the CAHPS® Hospice Survey, the anticipated HOPE tool, and use of Z codes on hospice claims.

Comment: Commenters stated that most hospice providers have not yet implemented initiatives to measure the impact of health equity initiatives with qualitative data. Some hospice providers stated that they collect qualitative social determinant of health information through admissions or social work assessments. Commenters requested guidance to support better qualitative data collection and analysis and sought examples of how this has been done. Several commenters requested consideration of the wide variety of existing support, infrastructure, and funding across hospice providers when determining support, flexibility, and requirements related to health equity measurement initiatives.

Response: CMS appreciates all stakeholder feedback received on this request for information. These comments will help inform CMS's future efforts to incorporate health equity and social determinants of health into the HQRP. CMS remains committed to creating meaningful quality measures based on robust and accurate data that follows the Meaningful Measures Framework and Blueprint, without imposing unnecessary burden on providers.

In addition, we sought comments on a future structural composite measure that would address aspects of health equity. Specifically, the structural composite measure could include organizational activities to address access to and the quality of hospice care for underserved populations. The composite structural measure concept could include hospice reported data on hospice activities to address underserved populations' access to hospice care. For example, a hospice could receive a point for each domain where data are submitted to a CMS portal, regardless of the hospice's action in that domain (such as, reporting whether or not the hospice provided training for board members, leaders, staff and volunteers in culturally and linguistically appropriate services (CLAS), health equity, and implicit bias). The data could reflect the hospice's completed actions for each corresponding domain (for a total of three points) in a reporting year. A hospice could submit information such as documentation, examples, or narratives to qualify for the measure numerator. We solicited comments on how to score a domain for a hospice that submitted data reflecting no actions or partial actions in the given domain.

Examples of the domains we considered are described in the following outline. We solicited comment on each of these domains.

Domain 1: Hospice commitment to reducing disparities is strengthened when equity is a key organizational priority. Candidate domain 1 could be satisfied when a hospice submits data on its actions regarding the role of health equity and community engagement in their strategic plan. Hospices could self-report data in the reporting year about their actions in each of the following areas, and submission of data for all elements could be required to qualify for the measure numerator.

- Hospice attests whether its strategic plan includes approaches to address health equity in the reporting year.
- Hospice reports community engagement and key stakeholder activities in the reporting year.
- Hospice reports on any attempts to measure input from patients and caregivers about care disparities it may experience and recommendations or suggestions.

Domain 2: Training board members, leaders, staff and volunteers in culturally and linguistically appropriate services (CLAS),[28] health equity, and implicit bias is an important step hospices take to provide quality care to diverse populations. Candidate domain 2 could focus on hospices' diversity, equity, inclusion and CLAS training for board members, employed staff, and volunteers by capturing the following self-reported actions in the reporting year. Submission of relevant data for all elements could be required to qualify for the measure numerator.

- Hospice attests whether employed staff were trained in CLAS and culturally sensitive care mindful of social determinants of health (SDOH) in the reporting year. Example data include specific training programs or training requirements for staff.
- Hospice attests whether it provided resources to staff and volunteers about health equity, SDOH, and equity

[28] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CLAS-Toolkit-12-7-16.pdf.*

initiatives in the reporting year. Examples include the materials provided, webinars, or learning opportunities.

Domain 3: Leaders and staff could improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. This candidate domain could capture activities related to organizational inclusion initiatives and capacity to promote health equity. Examples of equity-focused factors include proficiency in languages other than English, experience working with populations in the service area, experience working on health equity issues, and experience working with individuals with disabilities.

Submission of relevant data for all elements could be required to qualify for the measure numerator.

- Hospice attests whether equity-focused factors were included in the hiring of hospice senior leadership, including chief executives and board of trustees, in the previous reporting year.
- Hospice attests whether equity-focused factors were included in the hiring of hospice senior leadership, including chief executives and board of trustees, is more reflective of the services area patient than in the previous reporting year.
- Hospice attests whether equity-focused factors were included in the hiring of direct patient care staff (for example, RNs, medical social workers, aides, volunteers, chaplains, or therapists) in the previous reporting year.
- Hospice attests whether equity focused factors were included in the hiring of indirect care or support staff (for example. administrative, clerical, or human resources) in the previous reporting year.

We stated that we are interested in developing health equity measures based on information collected by hospices not currently available on claims, assessments, or other publicly available data sources to support development of future quality measures. We solicited public comments on the conceptual domains and quality measures described in this section. Furthermore, we solicited public comments on publicly reporting a composite structural health equity quality measure; displaying descriptive information on Care Compare from the data hospices provide to support health equity measures; and the impact of the domains and quality measure concepts on organizational culture change.

We received several comments regarding the request for information related to a health equity structural composite measure. A summary of the comments and our responses to those comments are as follows:

Comment: Commenters were generally supportive of developing a health equity structural composite measure but recommended a number of steps for CMS to take prior to implementation and publishing of the measure. Commenters emphasized the need to engage stakeholders and strongly supported the convening of a TEP to guide the development of the health equity structural composite measure. Several commenters also requested that providers have an opportunity to review, analyze, and learn from results of the structural measure prior to CMS implementation.

Comments focused on balancing administrative and resource burdens with the benefit of the information gathered. It was suggested that CMS leverage existing data collection tools and prioritize standardization of data collected across providers. Commenters also requested assurance that the data gathered be accurate, meaningful, and actionable. Several commenters recommended that the measure more explicitly incorporate social determinants of health data. Some commenters stated that there should be a focus on the impact of health equity-related activities on patient outcomes and disparities, in addition to the domains that are discussed.

Several commenters suggested that hospice providers will need tools such as trainings, improved health IT interoperability, or other additional resources, and sufficient time to incorporate a health equity framework into their daily practice prior to beginning data collection for a structural composite measure. This was especially highlighted as a concern for under-resourced providers serving smaller and rural communities. Additionally, commenters requested that CMS postpone public reporting of hospice health equity measures to allow for HOPE implementation, testing of health equity metrics in other settings of care, and pilot testing of the structural composite measure.

Comment: Commenters recognized strategic plans are a starting point to improve health equity, and supported a structural measure domain based on organizational commitment to health equity and community engagement in strategic planning. Some commenters recommended that CMS provide more specifics regarding information to be collected from the strategic plan, such as how disparities are being measured and by which tools. Some commenters encouraged CMS to ensure that measures related to this domain provide meaningful information about an organization's engagement and partnership with stakeholders. Commenters suggested measures such as providing education on the hospice benefit to targeted demographics, facilitating communication among providers and community partners, and finding ways to engage community members in nontraditional settings to reach patients who might not otherwise receive needed hospice care. There was also a concern that this domain would not assess whether outcomes are improved as a result of making equity a key organizational priority.

Some commenters suggested that the CAHPS® Hospice Survey could be revised to include additional questions regarding caregiver experience and recommendation for improvement, but also pointed out that caregivers may not be able to answer such questions due to limited exposure to hospice before hospice election. Commenters requested hospices be afforded the time and tools to incorporate a health equity framework into their daily practices before data collection for this domain commences. One commenter recommended that CMS develop standards related to this data collection, to facilitate hospice implementation. Another commenter requested the opportunity to provide feedback on the measure once developed and prior to public reporting of data for this domain. Additionally, some commenters suggested convening a TEP to further develop this domain.

Comment: Commenters generally supported and appreciated the attention toward culturally and linguistically appropriate services (CLAS) training and other health equity trainings. In addition to supporting cultural sensitivity efforts, several commenters recognized that efforts to improve organizational understanding of social determinants of health (SDOH) are equally needed. They recommended collecting data on SDOH and sociodemographic factors that may lead to poor outcomes. Specifically, respondents suggested collecting data on access to healthy foods, neighborhood safety, housing stability, income level, education quality, and transportation availability.

Regarding CLAS and health equity trainings, one commenter suggested requesting more specific information such as training content, frequency, training evaluation results, and any documentation of patient or family member experience with CLAS received. Some commenters suggested

CMS develop or approve evidence-based trainings and/or certification available without imposing a financial burden on hospices.

Comments were mixed when considering the collection of information for this domain, with some respondents asking for more detailed data collection requirements. There was some concern about the financial burden of providing additional trainings for certain staff. Lastly, there was a request to allow hospices a period of time to become familiar with CLAS and other health equity approaches prior to implementing required reporting for this domain.

Comment: Commenters were generally supportive of the concept of setting an organizational culture of equity and of considering health equity in hiring across all levels as a means of achieving equity. Some comments particularly highlighted the importance of incorporating equity-focused factors in the hiring of senior leadership roles. However, several commenters also noted that hiring practices are not the only area in which a culture of equity can be promoted. These comments stated that the current workforce shortages are leaving employers with limited applicant pools and reduced potential to give adequate weight to equity considerations during the hiring process. Given this context, these commenters stated that focusing solely on hiring practices may not be the most appropriate approach to assessing organizational culture of equity. Commenters offered several suggestions, such as evaluating existing staff capacity to address disparities, assessing patient profile concordance with community profile, and borrowing from proposed measures in hospital and skilled nursing facility settings for this domain.

Commenters recommended providing more specific definitions of each ''equity focused factor'' and asking hospice providers to report on each of the factors. Some commenters also recommended that a TEP be convened to guide the development of the measures for this domain. Lastly, some comments noted that organizational readiness and capacity may be difficult to achieve and CMS should allow hospices time to build a culture of equity prior to adopting this domain. To facilitate the institutionalization of a culture of equity, commenters recommended that CMS develop educational opportunities for providers and establish health equity board committees to provide resources and support providers' equity work.

Response: CMS appreciates the stakeholder comments received regarding a potential structural composite measure of health equity. Public input is very valuable for the continuing development of CMS' health equity quality measurement efforts and broader commitment to health equity; a key pillar of our strategic vision as further described here, *https://www.cms.gov/files/document/health-equity-fact-sheet.pdf.* CMS will take these questions and suggestions into consideration when further refining the measure concept. CMS remains committed to creating meaningful quality measures based on robust and accurate data that follows the Meaningful Measures Framework and Blueprint, without imposing unnecessary burden on providers. Continued stakeholder engagement and measure testing will be an important component of CMS's efforts to develop this structural measure.

7. Advancing Health Information Exchange Update

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with industry stakeholders to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) standards.[29] These standards could support the exchange and reuse of patient assessment data derived from the Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), Outcome and Assessment Information Set (OASIS), and other sources. The PACIO Project has focused on HL7 FHIR implementation guides for functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech Language, Swallowing, Cognitive communication and Hearing (SPLASCH) pathology. We encourage PAC provider and health IT vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2022 ISA is available at *https://www.healthit.gov/isa*.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) required HHS and ONC to take steps to further interoperability for providers and settings across the care continuum. Section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a trusted exchange framework and common agreement aimed at establishing full network-to-network exchange of health information nationally. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework [30] and Common Agreement Version 1.[31] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network Technical Framework Version 1 [32] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other—all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access

[29] *http://pacioproject.org/.*

[30] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[31] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[32] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

Services (IAS). For more information, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

We invited readers to learn more about these important developments and how they are likely to affect hospices.

Comment: We received several comments on the information provided in this section. Commenters expressed support for efforts across CMS and ONC to advance development of standards and certification for health IT promoting health information exchange focused on enhancing person-centered longitudinal care and exchange of clinical data. Commenters specifically recommended that CMS and ONC develop guidance and expectations around the collection and sharing of SDOH information for hospices and other post-acute care providers, as well as health IT vendors serving these providers, to ensure there are consistent requirements supporting interoperability of this data.

However, commenters identified a lack of interoperable health IT in hospices and other post-acute care settings as a major barrier to sharing health information quickly and easily across care settings. Commenters indicated that hospice and other post-acute care settings were not eligible for previous incentives to purchase technology certified under the ONC Health IT Certification Program, and that this has led to disparities in adoption between post-acute care and other settings that have received incentives. Commenters recommended that HHS continue to explore opportunities to use existing authorities to support technology adoption by hospice and other post-acute care providers in order to advance interoperability. Specific to exchange of SDOH information, commenters highlighted lack of clarity among stakeholders around how privacy rules apply to the sharing of this data as a potential barrier.

Finally, commenters provided a number of specific recommendations for new resources and enhancements to existing resources that HHS could pursue to assist hospice and other post-acute care providers with advancing data standardization.

Response: We appreciate the comments provided on interoperability initiatives and will take these comments into consideration as we coordinate with Federal partners, including ONC, on these initiatives, and to inform future rulemaking.

C. CAA 2021, Section 407. Establishing Hospice Program Survey and Enforcement Procedures Under the Medicare Program; Provisions Update

Division CC, section 407 of the CAA 2021, amended Part A of Title XVIII of the Act to add a new section 1822, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements, required public reporting of survey information, and a new hospice hotline.

This law (CAA 2021) requires public reporting of hospice program surveys conducted by both State Agencies (SAs) and Accrediting Organizations (AOs), as well as enforcement actions taken as a result of these surveys, on the CMS website in a manner that is prominent, easily accessible, searchable, and presented in a readily understandable format. It removes the prohibition at section 1865(b) of the Act of public disclosure of hospice surveys performed by AOs, and requires that AOs use the same survey deficiency reports as SAs (Form CMS–2567, ''Statement of Deficiencies'' or a successor form) to report survey findings.

The law also requires hospice programs to measure and reduce inconsistency in the application of survey results among all surveyors, and requires the Secretary to provide comprehensive training and testing of SA and AO hospice program surveyors, including training with respect to review of written plans of care. The statute prohibits SA surveyors from surveying hospice programs for which they have worked in the last 2 years or in which they have a financial interest, requires hospice program SAs and AOs to use a multidisciplinary team of individuals for surveys conducted with more than one surveyor to include at least one registered nurse, and provides that each SA must establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints.

The provisions in the CAA 2021 also direct the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, set out authority for imposing enforcement remedies for noncompliant hospice programs, and require the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These remedies can be imposed instead of, or in addition to, termination of the hospice programs' participation in the Medicare program. The remedies include civil money penalties (CMPs), suspension of all or part of payments, and appointment of temporary management to oversee operations.

In the CY 2022 Home Health Prospective Payment System (HH PPS) final rule (86 FR 62240), we addressed provisions related to the hospice survey enforcement and other activities described in this section. A summary of the finalized CAA provisions can be found in the CY 2022 HH PPS final rule: *https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf.* We finalized all the CAA provisions in CY 2022 rulemaking except for the SFP. As outlined in the CY 2022 HH PPS final rule, we stated that we would take into account comments that we received and work on a revised proposal, seeking additional collaboration with stakeholders to further develop the methodology for the SFP. Since the publication of the CY 2022 HH PPS final rule, we have decided to initiate a hospice Technical Expert Panel (TEP) in CY 2022. Accordingly, CMS plans to use the TEP findings to further develop a proposal on the methodology for establishing the hospice SFP, and we plan to include a proposal implementing an SFP in the FY 2024 Hospice Wage Index and Payment Rate Update proposed rule.

We received several comments regarding the SFP. A summary of those comments and our responses to those comments are as follows:

Comment: Commenters were generally supportive of CMS's efforts to establish an SFP and convene a TEP to provide feedback on a potential methodology for identifying hospices in the SFP. Many of these commenters expressed support for the inclusion of a wide range of stakeholders to be considered for TEP with knowledge related to the hospice survey process including hospice staff who directly interact with patients and surveyors.

A couple of commenters encouraged CMS to forgo the use of a quota system, as utilized in the Special Focus Facility (SFF) Program for nursing homes, in the new SFP for hospices. The commenters recommended CMS consider a national centralized SFP selection methodology rather than deferring to state priorities or agencies. Other commenters expressed support for standardizing the survey process, including standardizing surveyor training, before fully implementing the SFP to ensure there are no variances to how entities conduct their surveys.

Response: We appreciate the commenters support for the SFP. We will consider the comments and TEP feedback as CMS develops the SFP methodology.

V. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule meets the requirements of our regulations at § 418.306(c) and (d), which require annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of CBSAs or previously used MSAs, as well as any changes to the methodology for determining the per diem payment rates. This final rule also updates payment rates for each of the categories of hospice care, described in § 418.302(b), for FY 2023 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. Lastly, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this rule does not change the requirements for the HQRP in accordance with section 1814(i)(5) of the Act.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this final rule would result in an estimated increase of $825 million in payments to hospices, resulting from the hospice payment update percentage of 3.8 percent for FY 2023. The impact analysis of this rule represents the projected effects of the changes in hospice payments from FY 2022 to FY 2023. In order to calculate the wage index standardization factor, we simulate total payments using FY 2021 hospice utilization claims data; in this case claims accessed from the CCW on May 10, 2022 with the FY 2022 wage index (pre-floor, pre-reclassified hospital wage index with the hospice floor, without the 5-percent cap on wage index decreases) and FY 2022 payment rates, and compare it to our simulation of total payments using the FY 2023 hospice wage index (pre-floor, pre-reclassified hospital wage index with hospice floor, with the 5-percent cap on wage index decreases) and FY 2022 payment rates. By dividing payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the FY 2022 wage index and payment rates for each level of care by the FY 2023 wage index and FY 2022 payment rates, we obtain a wage index standardization factor for each level of care.

Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this final rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Hospice Payment Update for FY 2023

The FY 2023 hospice payment impacts appear in Table 10. We tabulate the resulting payments according to the classifications (for example, provider type, geographic region, facility size), and compare the difference between current and future payments to determine the overall impact. The first column shows the breakdown of all hospices by provider type and control (non-profit, for-profit, government, other), facility location, facility size. The second column shows the number of hospices in each of the categories in the first column. The third column shows the effect of using the FY 2023 updated wage index data with a 5-percent cap on wage index decreases. This represents the effect of moving from the FY 2022 hospice wage index to the FY 2023 hospice wage index with a 5-percent cap on wage index decreases. The aggregate impact of the changes in column three is zero percent, due to the hospice wage index standardization factor. However, there are distributional effects of the FY 2023 hospice wage index. The fourth column shows the effect of the hospice payment update percentage as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The hospice payment update percentage of 3.8 percent is based on the 4.1 percent inpatient hospital market basket update,

reduced by a 0.3 percentage point productivity adjustment. The fifth column shows the effect of all the changes on FY 2023 hospice payments. It is projected that aggregate payments would increase by 3.8 percent; assuming hospices do not change their billing practices. As illustrated in Table 10, the combined effects of all the proposals vary by specific types of providers and by location. We note that simulated payments are based on utilization in FY 2021 as seen on Medicare hospice claims (accessed from the CCW in May 10, 2022) and only include payments related to the level of care and do not include payments related to the service intensity add-on.

As illustrated in Table 10, the combined effects of all the proposals vary by specific types of providers and by location.

TABLE 10: Impact to Hospices for FY 2023

Hospice Subgroup	Hospices	FY 2023 Updated Wage Data With 5% Cap	FY 2023 Hospice Payment Update (%)	Overall Total Impact for FY 2023
All Hospices	5,253	0.0%	3.8%	3.8%
Hospice Type and Control				
Freestanding/Non-Profit	579	-0.1%	3.8%	3.7%
Freestanding/For-Profit	3,578	0.1%	3.8%	3.9%
Freestanding/Government	44	0.0%	3.8%	3.8%
Freestanding/Other	354	0.0%	3.8%	3.8%
Facility/HHA Based/Non-Profit	343	-0.2%	3.8%	3.6%
Facility/HHA Based/For-Profit	198	-0.2%	3.8%	3.6%
Facility/HHA Based/Government	77	-0.1%	3.8%	3.7%
Facility/HHA Based/Other	80	-0.3%	3.8%	3.5%
Subtotal: Freestanding Facility Type	4,555	0.0%	3.8%	3.8%
Subtotal: Facility/HHA Based Facility Type	698	-0.2%	3.8%	3.6%
Subtotal: Non-Profit	922	-0.1%	3.8%	3.7%
Subtotal: For Profit	3,776	0.1%	3.8%	3.9%
Subtotal: Government	121	-0.1%	3.8%	3.7%
Subtotal: Other	434	-0.1%	3.8%	3.7%
Hospice Type and Control: Rural				
Freestanding/Non-Profit	130	-0.1%	3.8%	3.7%
Freestanding/For-Profit	354	0.1%	3.8%	3.9%
Freestanding/Government	25	-0.5%	3.8%	3.3%
Freestanding/Other	51	0.1%	3.8%	3.9%
Facility/HHA Based/Non-Profit	133	-0.2%	3.8%	3.6%
Facility/HHA Based/For-Profit	50	-0.6%	3.8%	3.2%
Facility/HHA Based/Government	60	-0.1%	3.8%	3.7%
Facility/HHA Based/Other	46	-0.1%	3.8%	3.7%
Facility Type and Control: Urban				
Freestanding/Non-Profit	449	-0.1%	3.8%	3.7%
Freestanding/For-Profit	3,224	0.1%	3.8%	3.9%
Freestanding/Government	19	0.1%	3.8%	3.9%
Freestanding/Other	303	0.0%	3.8%	3.8%
Facility/HHA Based/Non-Profit	210	-0.2%	3.8%	3.6%
Facility/HHA Based/For-Profit	148	-0.1%	3.8%	3.7%

Facility/HHA Based/Government	17	-0.1%	3.8%	3.7%
Facility/HHA Based/Other	34	-0.3%	3.8%	3.5%
Hospice Location: Urban or Rural				
Rural	849	0.0%	3.8%	3.8%
Urban	4,404	0.0%	3.8%	3.8%
Hospice Location: Region of the Country (Census Division)				
New England	149	-0.5%	3.8%	3.3%
Middle Atlantic	282	0.2%	3.8%	4.0%
South Atlantic	592	-0.3%	3.8%	3.5%
East North Central	569	-0.4%	3.8%	3.4%
East South Central	258	-0.1%	3.8%	3.7%
West North Central	413	-0.4%	3.8%	3.4%
West South Central	1,030	0.5%	3.8%	4.3%
Mountain	548	-0.1%	3.8%	3.7%
Pacific	1,363	0.6%	3.8%	4.4%
Outlying	49	-0.3%	3.8%	3.5%
Hospice Size				
0 - 3,499 RHC Days (Small)	1,133	0.3%	3.8%	4.1%
3,500-19,999 RHC Days (Medium)	2,462	0.2%	3.8%	4.0%
20,000+ RHC Days (Large)	1,658	0.0%	3.8%	3.8%

Source: FY 2021 hospice claims data from CCW accessed on May 10, 2022.
Note: The overall total impact reflects the addition of the individual impacts, which includes the overall wage index impact of updating the wage data with a 5-percent cap on wage index decreases, as well as the 3.8 percent hospice payment update percentage which reflects the productivity-adjusted hospital market basket.

Region Key:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**= Alaska, California, Hawaii, Oregon, Washington
Outlying=Guam, Puerto Rico, Virgin Islands

2. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on ~~last~~ this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed ~~last~~ this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the occupational wage information from the BLS for medical and health service managers (Code 11–9111) from May 2020; we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe

benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). This rule consists of approximately 29,289 words. Assuming an average reading speed of 250 words per minute, it would take approximately 0.98 hours for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is $112.49 (0.98 hours × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $8,211.72 ($112.49 × 73 reviewers).

D. Alternatives Considered

Since the hospice payment update percentage is determined based on statutory requirements, we did not consider not updating hospice payment rates by the payment update percentage. The 3.8 percent hospice payment update percentage for FY 2023 is based on a 4.1 percent inpatient hospital market basket update, reduced by a 0.3 percentage point productivity adjustment. Payment rates since FY 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent years must be the market basket percentage for that FY. Section 3401(g) of the Affordable Care Act also mandates that, starting with FY 2013 (and in subsequent years), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table 11, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. Table 11 provides our best estimate of the possible changes in Medicare payments under the hospice benefit as a result of the policies in this rule. This estimate is based on the data for 5,253 hospices in our impact analysis file, which was constructed using FY 2021 claims available in May 2022. All expenditures are classified as transfers to hospices.

TABLE 11: Accounting Statement: Classification of Estimated Transfers and Costs, From FY 2022 to FY 2023

Category	Transfers
Annualized Monetized Transfers	$ 825 million*
From Whom to Whom?	Federal Government to Medicare Hospices

*The increase of $825 million in transfer payments is a result of the 3.8 percent hospice payment update compared to payments in FY 2022.

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We consider all hospices as small entities as that term is used in the RFA. The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the United States business economy. There is no NAICS code specific to hospice services. Therefore, we utilized the NAICS United States industry title ''Home Health Care Services'' and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of $16.5 million.[33] Table 12 shows the number of firms, revenue, and estimated impact per home health care service category.

[33] *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

TABLE 12: NUMMBER OF FIRMS, REVENUE, AND ESTIMATED IMPACT OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS Code	NAICS Description	Enterprise Size	Number of Firms	Receipts ($1,000)	Estimated Impact ($1,000) per Enterprise Size
621610	Home Health Care Services	<100	5,861	210,697	$35.95
621610	Home Health Care Services	100-499	5,687	1,504,668	$264.58
621610	Home Health Care Services	500-999	3,342	2,430,807	$727.35
621610	Home Health Care Services	1,000-2,499	4,434	7,040,174	$1,587.77
621610	Home Health Care Services	2,500-4,999	1,951	6,657,387	$3,412.29
621610	Home Health Care Services	5,000-7,499	672	3,912,082	$5,821.55
621610	Home Health Care Services	7,500-9,999	356	2,910,943	$8,176.81
621610	Home Health Care Services	10,000-14,999	346	3,767,710	$10,889.34
621610	Home Health Care Services	15,000-19,999	191	2,750,180	$14,398.85
621610	Home Health Care Services	≥20,000	961	51,776,636	$53,877.87
621610	Home Health Care Services	Total	23,801	82,961,284	$3,485.62

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2017" (SOURCE: 2017 County Business Patterns and Economic Census) Release Date: 5/28/2021: https://www2.census.gov/programs-surveys/susb/tables/2017/
Notes: Estimated impact is calculated as Receipts ($1,000)/Number of firms.

The Department of Health and Human Services practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of hospice visits are Medicare paid visits and therefore the majority of hospice's revenue consists of Medicare payments. Based on our analysis, we conclude that the policies finalized in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of hospices. Therefore, the Secretary has determined that this hospice final rule would have significant economic impact on a substantial number of small entities. We estimate that the net impact of the policies in this rule is a 3.8 percent or approximately $825 million in increased revenue to hospices in FY 2023. The 3.8 percent increase in expenditures when comparing FY 2023 payments to estimated FY 2022 payments is reflected in the last column of the first row in Table 10 and is driven solely by the impact of the hospice payment update percentage reflected in the fourth column of the impact table. In addition, small hospices would experience a greater estimated increase (4.1 percent), compared to large hospices (3.8 percent) due to the policy to cap wage index decreases at 5 percent. Further detail is presented in Table 10, by hospice type and location.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This rule will only affect hospices; therefore, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals (see Table 10).

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $165 million or more in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

I. Conclusion

We estimate that aggregate payments to hospices in FY 2023 will increase by $825 million as a result of the market basket update, compared to payments in FY 2022. We estimate that in FY 2023, hospices in both rural and urban areas will experience, on average, a 3.8 percent increase in estimated payments compared to FY 2022. Hospices providing services in the Pacific and West South Central regions would experience the largest estimated increases in payments of 4.4 percent and 4.3 percent, respectively. Hospices serving patients in areas in the New England region would experience, on average, the lowest estimated increase of 3.3 percent in FY 2023 payments.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 22, 2022.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 418 as set forth below.

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section § 418.306 is amended by revising paragraph (c) to read as follows:

§ 418.306 Annual update of the payment rates and adjustment for area wage differences.

* * * * *

(c) *Adjustment for wage differences.* (1) Each hospice's labor market is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by OMB. CMS will issue annually, in the **Federal Register**, a hospice wage index based on the most current available CMS hospital wage data, including changes to the definition of MSAs. The urban and rural area geographic classifications are defined in § 412.64(b)(1)(ii)(A) through (C) of this chapter. The payment rates established by CMS are adjusted by the Medicare contractor to reflect local differences in wages according to the revised wage data.

(2) Beginning on October 1, 2022, CMS applies a cap on decreases to the hospice wage index such that the wage index applied to a geographic area is not less than 95 percent of the wage index applied to that geographic area in the prior fiscal year.

* * * * *

Dated: July 25, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–16214 Filed 7–27–22; 4:15 pm]

BILLING CODE 4120–01–P

Proposed Rules

Federal Register
Vol. 87, No. 145
Friday, July 29, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 431

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Intent To Establish a Working Group for Commercial Unitary Air Conditioners and Heat Pumps To Negotiate a Notice of Proposed Rulemaking for Test Procedures and Energy Conservation Standards

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of intent and solicitation of nominations for membership.

SUMMARY: The U.S. Department of Energy (''DOE'' or ''the Department'') is giving notice that DOE intends to establish a negotiated rulemaking working group under the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') in accordance with the Federal Advisory Committee Act (''FACA'') and the Negotiated Rulemaking Act (''NRA'') to negotiate proposed test procedures and amended energy conservation standards commercial unitary air conditioners and heat pumps (''CUACs and CUHPs''). The purpose of the working group will be to discuss and, if possible, reach consensus on a proposed rule regarding test procedures and energy conservation standards for CUACs and CUHPs, as authorized by the Energy Policy and Conservation Act, as amended (''EPCA''). The working group will consist of representatives of parties having a defined stake in the outcome of the proposed standards and/or test procedure, and will consult as appropriate with a range of experts on technical issues. DOE is hereby soliciting nominations for members of the CUAC and CUHP working group. Application packages should be submitted to DOE by August 12, 2022.

DATES: Nominations of membership must be received on or before August 12, 2022. DOE will not consider any nominations received via mail or after midnight on August 12, 2022.

ADDRESSES: The nominee's name, resume, biography, and any letters of support must be submitted in electronic format via email to *asrac@ee.doe.gov.* Any requests for further information should also be sent via email to *asrac@ee.doe.gov*

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–7335. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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II. Background
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I. Authority

DOE is announcing its intent to negotiate proposed test procedures and amended energy conservation standards for CUACs and CUHPs under the authority of sections 563 and 564 of the NRA (5 U.S.C. 561–570, Pub. L. 104–320). DOE is seeking to develop proposals to amend the current test procedures and standards through a negotiated rulemaking process under the authority of EPCA, 42 U.S.C. 6311(1) and 42 U.S.C. 6291 *et seq.*

II. Background

On July 21, 2022, the ASRAC met and made a recommendation to form a CUAC and CUHP subcommittee to meet, discuss, and, if possible, reach consensus on a proposed rule for the test procedures and energy efficiency standards for CUACs and CUHPs. For purposes of this document, the ASRAC subcommittee at issue will be referred to as the ''working group.'' As required by the NRA, DOE is giving notice that it is establishing a working group under ASRAC to discuss proposed amended test procedures and energy efficiency requirements for CUACs and CUHPs. The working group will be established and function as a subcommittee of ASRAC in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. 2.

A. Negotiated Rulemaking

DOE is supporting the use of the negotiated rulemaking process to discuss and develop proposed test procedures and amended energy conservation standards for CUACs and CUHPs. The primary reason for using the negotiated rulemaking process for this equipment is that stakeholders strongly support a consensual rulemaking effort. DOE believes such a regulatory negotiation process will be less adversarial and better suited to resolving complex technical issues. An important virtue of negotiated rulemaking is that it allows expert dialog that is much better than traditional techniques at getting the facts and issues right and will result in a proposed rule that will effectively reflect Congressional intent.

A regulatory negotiation will enable DOE to engage in direct and sustained dialog with informed, interested, and affected parties when drafting the regulation, rather than obtaining input during a public comment period after developing and publishing a proposed rule. A rule drafted by negotiation with informed and affected parties is expected to be potentially more pragmatic and more easily implemented than a rule arising from the traditional process. Such rulemaking improvement is likely to provide the public with the full benefits of the rule while minimizing the potential negative impact of a proposed regulation conceived or drafted without the full prior input of outside knowledgeable parties. Because a negotiating working group includes representatives from the major stakeholder groups, including consumers, affected by or interested in the rule, the number of public comments on the proposed rule may be decreased. DOE anticipates that there will be a need for fewer substantive changes to a proposed rule developed under a regulatory negotiation process prior to the publication of a final rule.

B. The Concept of Negotiated Rulemaking

Usually, DOE develops a proposed rulemaking using Department staff and consultant resources. Congress noted in the NRA, however, that regulatory development may ''discourage the affected parties from meeting and

communicating with each other, and may cause parties with different interests to assume conflicting and antagonistic positions * * *.'' 5 U.S.C. 561(2)(2). Congress also stated that ''adversarial rulemaking deprives the affected parties and the public of the benefits of face-to-face negotiations and cooperation in developing and reaching agreement on a rule. It also deprives them of the benefits of shared information, knowledge, expertise, and technical abilities possessed by the affected parties.'' 5 U.S.C. 561(2)(3).

Using negotiated rulemaking to develop a proposed rule differs fundamentally from the Department centered process. In negotiated rulemaking, a proposed rule is developed by an advisory committee or a working group established by the advisory committee, in accordance with the provisions of FACA, 5 U.S.C. App. 2, composed of members chosen to represent the various interests that will be significantly affected by the rule. The goal of the advisory committee or its working group is to reach consensus on the treatment of the major issues involved with the rule. The process starts with the Department's careful identification of all interests potentially affected by the rulemaking under consideration. To help with this identification, the Department publishes a notice of intent such as this one in the **Federal Register**, identifying a preliminary list of interested parties and requesting public comment on that list. Following receipt of comments, the Department establishes an advisory committee or advisory committee working group representing the full range of stakeholders to negotiate a consensus on the terms of a proposed rule. Representation on the advisory committee or its working group may be direct; that is, each member may represent a specific interest, or may be indirect, such as through trade associations and/or similarly situated parties with common interests. The Department is a member of the advisory committee or working group and represents the Federal government's interests. The advisory committee or working group chair is assisted by a neutral mediator who facilitates the negotiation process. The role of the mediator, also called a facilitator, is to apply proven consensus-building techniques to the advisory committee or working group process.

If the advisory committee itself is undertaking the negotiation, once the committee reaches consensus on the provisions of a proposed rule and recommends such consensus to the Department, the Department, consistent with its legal obligations, may use such consensus as the basis of its proposed rule, which then is published in the **Federal Register**. If a working group of the advisory committee is undertaking the negotiation, once the working group reaches consensus on the provisions of a proposed rule, a recommendation is made to the advisory committee. The advisory committee may then, consistent with its legal obligations, use such consensus as the basis for making a recommendation to the Department of a proposed rule. The Department, consistent with its legal obligations, may use such consensus as the basis of its proposed rule, which then is published in the **Federal Register**. This publication provides the required public notice and provides for a public comment period. Other participants and other interested parties retain their rights to comment, participate in an informal hearing (if requested), and request judicial review. DOE anticipates, however, that the preproposal consensus agreed upon by the advisory committee will narrow any issues in the subsequent rulemaking.

C. Proposed Rulemaking for Test Procedures and Energy Conservation Standards and Energy Conservation Standards Regarding CUACs and CUHPs

The NRA enables DOE to establish an advisory committee or working group under the advisory committee if it is determined that the use of the negotiated rulemaking process is in the public interest. DOE intends to develop Federal regulations that build on the depth of experience accrued in both the public and private sectors in implementing standards and programs.

DOE is supporting the use of the regulatory negotiation process in order to provide for obtaining a diverse array of in-depth input, as well as an opportunity for increased collaborative discussion from both private-sector stakeholders and government officials who are familiar with the energy efficiency of CUACs and CUHPs.

D. Department Commitment

In initiating this regulatory negotiation process to develop test procedures and amended energy conservation standards for CUACs and CUHPs, DOE is making a commitment to provide adequate resources to facilitate timely and successful completion of the process. This commitment includes making the process a priority activity for all representatives, components, officials, and personnel of the Department who need to be involved in the rulemaking, from the time of initiation until such time as a final rule is issued or the process is expressly terminated. DOE will provide administrative support for the process and will take steps to ensure that the advisory committee or its working group has the dedicated resources it requires to complete its work in a timely fashion. Specifically, DOE will make available the following support services: properly equipped space adequate for public meetings and caucuses; logistical support; word processing and distribution of background information; the service of a facilitator; and such additional research and other technical assistance as may be necessary. All meetings will provide an opportunity for all members of the working group and other interested parties to participate by webinar. While DOE strongly encourages members to participate in person, DOE realizes that travel costs may prohibit in-person attendance. Prospective members, therefore, should not allow travel costs to affect their decision to apply for membership.

To the maximum extent possible consistent with the legal obligations of the Department, DOE will use the consensus of the advisory committee as the basis for the rule the Department proposes for public notice and comment.

E. Negotiating Consensus

As discussed, the negotiated rulemaking process differs fundamentally from the usual process for developing a proposed rule. Negotiation enables interested and affected parties to discuss various approaches to issues rather than asking them only to respond to a proposal developed by the Department. The negotiation process involves a mutual education of the various parties on the practical concerns about the impact of standards. Each advisory committee or working group member participates in resolving the interests and concerns of other members, rather than leaving it up to DOE to evaluate and incorporate different points of view.

A key principle of negotiated rulemaking is that agreement is by consensus of all the interests. Thus, no one interest, or group of interests is able to control the process. The NRA defines consensus as the unanimous concurrence among interests represented on a negotiated rulemaking committee or working group, unless the committee or its working group itself unanimously agrees to use a different definition. 5 U.S.C. 562. In addition, experience has demonstrated that using a trained mediator to facilitate this

process will assist all parties, including DOE, in identifying their real interests in the rule, and thus will enable parties to focus on and resolve the important issues.

III. Proposed Negotiating Procedures

A. Key Issues for Negotiation

The following issues and concerns will underlie the work of the Negotiated Rulemaking Committee on CUACs and CUHPs:

- Test procedures for CUACs and CUHPs; and
- Energy Conservation Standards for CUACs and CUHPs.

To examine the underlying issues outlined above, and others not yet articulated, all parties in the negotiation will need DOE to provide data and an analytic framework complete and accurate enough to support their deliberations. DOE's analyses must be adequate to inform a prospective negotiation.

B. Formation of Working Group

A working group will be formed and operated in full compliance with the requirements of FACA and in a manner consistent with the requirements of the NRA. DOE has determined that the working group shall not exceed 25 members. The Department believes that more than 25 members would make it difficult to conduct effective negotiations. DOE is aware that there may be many more potential participants than there are membership slots on the working group. The Department does not believe, nor does the NRA contemplate, that each potentially affected group must participate directly in the negotiations; nevertheless, each affected interest can be adequately represented. To have a successful negotiation, it is important for interested parties to identify and form coalitions that adequately represent significantly affected interests. To provide adequate representation, those coalitions must agree to support, both financially and technically, a member of the working group whom they choose to represent their interests.

DOE recognizes that when it establishes or amends energy efficiency standards and test procedures for residential products and commercial equipment, various segments of society may be affected in different ways, in some cases producing unique ''interests'' in a proposed rule based on income, gender, or other factors. The Department will pay attention to providing that any unique interests that have been identified, and that may be significantly affected by the proposed rule, are represented.

FACA also requires that members of the public have the opportunity to attend meetings of the full committee and speak or otherwise address the committee during the public comment period. In addition, any member of the public is permitted to file a written statement with the advisory committee. DOE plans to follow these same procedures in conducting meetings of the working group.

C. Interests Involved/Working Group Membership

DOE anticipates that the working group will comprise no more than 25 members who represent affected and interested stakeholder groups, at least one of whom must be a member of the ASRAC. As required by FACA, the Department will conduct the negotiated rulemaking with particular attention to ensuring full and balanced representation of those interests that may be significantly affected by the proposed rule amending standards for CUACs and CUHPs. Section 562 of the NRA defines the term ''interest'' as ''with respect to an issue or matter, multiple parties which have a similar point of view or which are likely to be affected in a similar manner.'' Listed are parties the Department to date has identified as being ''significantly affected'' by a proposed rule regarding the energy efficiency of CUACs and CUHPs.

- The Department of Energy;
- States;
- Trade associations representing installers and distributors of CUACs and CUHPs;
- Heating and cooling system designers and engineers;
- Component manufacturers and related suppliers;
- Utilities;
- Energy efficiency/environmental advocacy groups;
- Commercial building owners; and
- Commercial building tenants.

One purpose of this notice of intent is to determine whether Federal regulations for CUACs and CUHPs will significantly affect interests that are not listed previously. DOE invites comment and suggestions on its initial list of significantly affected interests and encourages all interested parties and interests to apply for the Working Group.

Members may be individuals or organizations. If the effort is to be fruitful, participants on the working group should be able to fully and adequately represent the viewpoints of their respective interests. This document gives notice of DOE's process to other potential participants and affords them the opportunity to request representation in the negotiations. Those who wish to nominate members to the working group, should submit an application package to DOE, in accordance with the public participation procedures outlined in the **DATES** and **ADDRESSES** sections of this notice of intent. Qualified individuals can self-nominate or be nominated by any individual or organization. Nominators should submit an application package which includes:

- The nominee's current resume or curriculum vitae and contact information, including mailing address, email address, and telephone number;
- A letter of interest, which includes:
  - A summary of how the nominee's experience and expertise would support the working group's objectives;
  - The interest the nominee would represent in the working group; and
  - A description of other assets (such as data or modeling tools) the nominee could provide to support the working group's objectives.

Membership of the working group is likely to involve:

- Attendance (in person preferable) at approximately ten (10), one (1)- to two (2)- day meetings (with the potential for two (2) additional one (1)- or two (2)-day meetings);
- Travel costs to those meetings, if participating in person; and
- Preparation time for those meetings.

Members serving on the working group will not receive compensation for their services. Interested parties who are not selected for membership on the working group may make valuable contributions to this negotiated rulemaking effort in any of the following ways:

- The person may request to be placed on the working group mailing list and submit written comments as appropriate.
- The person may attend working group meetings, which are open to the public; caucus with his or her interest's member on the working group; or even address the working group during the public comment portion of the working group meeting.
- The person could assist the efforts of a workgroup that the working group might establish.

A working group may establish informal workgroups, which usually are asked to facilitate committee deliberations by assisting with various technical matters (*e.g.,* researching or preparing summaries of the technical literature or comments on specific matters such as economic issues). Workgroups also might assist in estimating costs or drafting regulatory

text on issues associated with the analysis of the costs and benefits addressed, or formulating drafts of the various provisions and their justifications as previously developed by the working group. Given their support function, workgroups usually consist of participants who have expertise or particular interest in the technical matter(s) being studied. Because it recognizes the importance of this support work for the working group, DOE will provide appropriate technical expertise for such workgroups.

D. Good Faith Negotiation

Every working group member must be willing to negotiate in good faith and have the authority, granted by his or her constituency, to do so. The first step is to ensure that each member has good communications with his or her constituencies. An intra-interest network of communication should be established to bring information from the support organization to the member at the table, and to take information from the table back to the support organization. Second, each organization or coalition therefore should designate as its representative a person having the credibility and authority to ensure that needed information is provided and decisions are made in a timely fashion. Negotiated rulemaking can require the appointed members to give a significant sustained time commitment for as long as the duration of the negotiated rulemaking. Other qualities of members that can be helpful are negotiating experience and skills, familiarity with using CUACs and CUHPs systems as a consumer, and/or sufficient technical knowledge to participate in substantive negotiations.

Certain concepts are central to negotiating in good faith. One is the willingness to bring all issues to the bargaining table in an attempt to reach a consensus, as opposed to keeping key issues in reserve. The second is a willingness to keep the issues at the table and not take them to other forums. Finally, good faith includes a willingness to move away from some of the positions often taken in a more traditional rulemaking process, and instead explore openly with other parties all ideas that may emerge from the working group's discussions.

E. Facilitator

The facilitator will act as a neutral in the substantive development of the proposed standard. The facilitator's role generally includes:

- Impartially assisting the members of the working group in conducting discussions and negotiations; and
- Impartially assisting in performing the duties of the Designated Federal Official under FACA.

F. Department Representative

The DOE representative will be a full and active participant in the consensus building negotiations. The Department's representative will meet regularly with senior Department officials, briefing them on the negotiations and receiving their suggestions and advice so that he or she can effectively represent the Department's views regarding the issues before the working group. DOE's representative also will ensure that the entire spectrum of governmental interests affected by the standards rulemaking, including the Office of Management and Budget, the Attorney General, and other Departmental offices, are kept informed of the negotiations and encouraged to make their concerns known in a timely fashion.

G. Working Group and Schedule

After evaluating the comments submitted in response to this notice of intent and the requests for nominations, DOE will either inform the members of the working group that they have been selected or determine that conducting a negotiated rulemaking is inappropriate.

The working group is expected to make a concerted effort to negotiate a first term sheet on the test procedure and a second term sheet on energy conservation standards within six (6) months of its first meeting. The working group's negotiations will take place around two discrete tasks. The test procedure term sheet, if completed, is to be approved by the working group and transmitted to ASRAC prior to commencement of negotiations regarding the energy conservation standards. At the completion of the negotiations for each discrete task, the term sheet, if completed, will be presented to ASRAC at an open meeting for its deliberation and decision on whether to approve it and submit it to DOE as a formal recommendation.

DOE will advise working group members of administrative matters related to the functions of the working group before beginning. While the negotiated rulemaking process is underway, DOE is committed to performing much of the same analysis as it would during a normal standards rulemaking process and to providing information and technical support to the working group.

IV. Comments Requested

DOE requests comments on which parties should be included in a negotiated rulemaking to develop draft language pertaining to the energy efficiency of CUACs and CUHPs and suggestions of additional interests and/or stakeholders that should be represented on the working group. All who wish to participate as members of the working group should submit a request for nomination to DOE.

V. Public Participation

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of intent and solicitation of nominations for membership.

Signing Authority

This document of the Department of Energy was signed on July 25, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 26, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–16291 Filed 7–28–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0984; Project Identifier MCAI–2022–00236–T]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Embraer S.A. Model EMB–545 airplanes. This proposed AD was prompted by an error that was detected in the airplane takeoff configuration warning logic. The error prevents the system from sounding an aural alert ''No Takeoff Trim'' for the flightcrew. This proposed AD would require installation of a new software version of engine indication and crew alert system (EICAS), as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 12, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.* You may find this material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0984.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0984; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Ho-Joon Lim, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3405; email *Ho-Joon.Lim@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0984; Project Identifier MCAI–2022–00236–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Ho-Joon Lim, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206 231 3405; email *Ho-Joon.Lim@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

ANAC, which is the aviation authority for Brazil, has issued AD 2022–02–02, effective February 23, 2022 (ANAC AD 2022–02–02) (also referred to as the MCAI), to correct an unsafe condition for certain Embraer S.A. Model EMB–545 airplanes.

This proposed AD was prompted by an error that was detected in the airplane takeoff configuration warning logic. The error prevents the system from sounding an aural alert ''No Takeoff Trim'' for the flightcrew, if the pitch trim is in a position that would not allow a safe takeoff (positioned out of the green band indication). The FAA is proposing this AD to address the lack of the aural alert ''No Takeoff Trim'' to the flightcrew on a possibly misconfigured airplane, which could result in loss of airplane controllability. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

ANAC AD 2022–02–02 specifies procedures for installation of a new software version of EICAS.

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in ANAC AD 2022–02–02 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate ANAC AD 2022–02–02 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with ANAC AD 2022–02–02 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by ANAC AD 2022–02–02 for compliance will be available at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0984 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 41 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3.5 work-hours × $85 per hour = $297.50	(*)	$297.50	$12,197.50

* The FAA has received no definitive data on which to base the cost estimates for the parts specified in this proposed AD.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Embraer S.A.: Docket No. FAA–2022–0984; Project Identifier MCAI–2022–00236–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 12, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model EMB–545 airplanes, certificated in any category, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2022–02–02, effective February 23, 2022 (ANAC AD 2022–02–02).

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Unsafe Condition

This AD was prompted by an error that was detected in the airplane takeoff configuration warning logic. The error prevents the system from sounding an aural

alert ''No Takeoff Trim'' for the flightcrew, if the pitch trim is in a position that would not allow a safe takeoff (positioned out of the green band indication). The FAA is issuing this AD to address the lack of sound aural alert ''No Takeoff Trim'' to the flightcrew on a possibly misconfigured airplane, which could result in loss of airplane controllability.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2022–02–02.

(h) Exceptions to ANAC AD 2022–02–02

(1) Where ANAC AD 2022–02–02 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Alternative methods of compliance (AMOC)'' section of ANAC AD 2022–02–02 does not apply to this AD.

(3) Where paragraph (b) of ANAC AD 2022–02–02 specifies acceptable higher software versions, replace ''For higher software versions, use the applicable Service Bulletin recommended by the Manufacturer'' with ''For higher software versions, use the applicable Service Bulletin approved by ANAC and recommended by the Manufacturer.''

(i) No Reporting Required

Although the service information referenced in ANAC AD 2022–02–02 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(k) Related Information

(1) For ANAC AD 2022–02–02, contact National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0984.

(2) For more information about this AD, contact Ho-Joon Lim, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone 206–231–3405; email *Ho-Joon.Lim@faa.gov.*

Issued on July 26, 2022.

Christina Underwood,

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

[FR Doc. 2022–16275 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0981; Project Identifier MCAI–2022–00032–T]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This proposed AD was prompted by reports of flight control (horizontal stabilizer, rudder, and elevator) decals degrading and peeling (damage), reports of operators painting over these decals, and reports that procedures to replace these decals were inaccurate, potentially causing incorrect positioning of replacement decals. This proposed AD would require inspecting the left and right horizontal stabilizer decals for visibility and damage; and for certain airplanes, inspecting the rudder and left and right elevator decals for visibility and damage; and doing applicable corrective actions, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 12, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0981.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0981; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative

Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *gabriel.d.kim@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0981; Project Identifier MCAI–2022–00032–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *gabriel.d.kim@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2022–01, dated January 7, 2022 (TCCA AD CF–2022–01) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes.

This proposed AD was prompted by reports of flight control decals degrading and peeling, reports of operators painting over these decals, and reports that procedures to replace these decals were inaccurate, potentially causing incorrect positioning of replacement decals. An investigation determined that the degradation and peeling of the flight control decals was caused by an incorrect clear protective coating being applied during production, and that flight control decals were being painted over because of unclear in-service procedures. Additionally, the in-service procedures used for replacing these decals were not accurate, potentially causing incorrect positioning of the replacement decals. The in-service procedures were revised to clearly state that the flight control decals are to be masked prior to painting, and to ensure the flight control decals are properly placed going forward.

The FAA is proposing this AD to address flight control decals that are damaged or incorrectly positioned, which could introduce rigging offset of flight control surfaces, and when combined with other failures or severe maneuvers, could result in loss of flight control surface effectiveness or structural loading that exceeds the airframe's capability. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

TCCA CF–2022–01 specifies procedures for inspecting the left and right horizontal stabilizer decals for visibility and damage, and corrective actions. For certain airplanes, TCCA CF–2022–01 specifies procedures for inspecting the rudder and left and right elevator decals for visibility and damage. The corrective actions include replacing, restoring, and preserving the condition and placement of the flight control decals, and re-rigging the rudder and elevator control surfaces. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in TCCA AD CF–2022–01 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate TCCA AD CF–2022–01 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with TCCA AD CF–2022–01 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by TCCA AD CF–2022–01 for compliance will be available at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0981 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 56 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
10 work-hours × $85 per hour = $850	$0	$850	$47,600

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
4 work-hours × $85 per hour = $340	$220	$560

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

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Docket No. FAA–2022–0981; Project Identifier MCAI–2022–00032–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 12, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada Civil Aviation (TCCA) AD CF–2022–01, dated January 7, 2022 (TCCA AD CF–2022–01).

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of flight control (horizontal stabilizer, rudder, and elevator) decals degrading and peeling (damage), reports of operators painting over these decals, and reports that procedures to replace these decals were inaccurate, potentially causing incorrect positioning of replacement decals. The FAA is issuing this AD to address flight control decals that are damaged or incorrectly positioned, which could introduce rigging offset of flight control surfaces, and when combined with other failures or severe maneuvers, could result in loss of flight control surface effectiveness or structural loading that exceeds the airframe's capability.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, TCCA AD CF–2022–01.

(h) Exceptions to TCCA AD CF–2022–01

(1) Where TCCA AD CF–2022–01 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where TCCA AD CF–2022–01 refers to ''hours air time,'' this AD requires using ''flight hours.''

(i) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal

inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

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

(j) Related Information

(1) For TCCA AD CF–2022–01, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0981.

(2) For more information about this AD, contact Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *gabriel.d.kim@faa.gov.*

Issued on July 22, 2022.

Christina Underwood,

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

[FR Doc. 2022–16099 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0982; Project Identifier MCAI–2021–00787–T]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This proposed AD was prompted by reports that the engine feed pressure switches were installed with no secondary locking mechanism and can become loose and cause a fuel leak. This proposed AD would require initial and repetitive inspections at the engine feed pressure switch locations and installation of a flange adaptor with lockwire to terminate the repetitive inspection, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 12, 2022

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

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

For material that will be incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0982.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0982; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Joseph Catanzaro, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7366; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0982; Project Identifier MCAI–2021–00787–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial

information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Joseph Catanzaro, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7366; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2021–50, dated December 21, 2021 (TCCA AD CF–2021–50) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes.

This proposed AD was prompted by reports that certain fuel system pressure switches have been installed without a secondary locking feature (lockwire). The fuel pressure switches are installed on the alternating current (AC) boost pump cartridge located in the wing dry bay (outboard of rib 6) and near the engine feed pressure switch, on the rear spar (between ribs 8 and 9). Both installations exist on the left-hand and right-hand wings for a total of four affected locations on the airplane. The FAA is proposing this AD to address the absence of a secondary locking feature (lockwire) on the fuel pressure switches, which may allow them to become loose and allow fuel to leak in the affected areas, creating a fire hazard. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

TCCA AD CF–2021–50 specifies procedures for repetitive general visual inspections of the torque identification stripes, torquing of the fuel pressure switches, and installation of lockwire at the two AC boost pump cartridges; repetitive general visual inspections of the torque identification stripes and torquing of the fuel pressure switches at the two engine feed pressure switches; and installation of a new flange adaptor and lockwire, which terminates the repetitive inspections. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in TCCA AD CF–2021–50 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate TCCA AD CF–2021–50 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with TCCA AD CF–2021–50 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by TCCA AD CF–2021–50 for compliance will be available at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0982 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 60 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 27 work-hours × $85 per hour = $2,295	$811	Up to $2,295 ..	$137,700

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
14 work-hours × $85 per hour = $1,190	$0	$1,190

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Docket No. FAA–2022–0982; Project Identifier MCAI–2021–00787–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 12, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada Civil Aviation (TCCA) AD CF–2021–50, dated December 21, 2021 (TCCA AD CF–2021–50).

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by reports that the engine feed pressure switches were installed with no secondary locking mechanism and can become loose and cause a fuel leak. The FAA is issuing this AD to address the absence of a secondary locking feature (lockwire) on the fuel pressure switches, which may allow them to become loose and allow fuel to leak in the affected areas, creating a fire hazard.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, TCCA AD CF–2021–50.

(h) Exception to TCCA AD CF–2021–50

(1) Where TCCA AD CF–2021–50 refers to hours air time, this AD requires using flight hours.

(2) Where TCCA AD CF–2021–50 refers to its effective date, or 14 July 2021, the effective date of AD CF–2021–21, this AD requires using the effective date of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) For TCCA AD CF–2021–50, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0982.

(2) For more information about this AD, contact Joseph Catanzaro, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7366; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on July 22, 2022.

Christina Underwood,

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

[FR Doc. 2022–16100 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0015; Project Identifier AD–2021–00832–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that would have applied to certain Airbus Helicopters Model EC225LP helicopters. This action revises the NPRM by removing the requirement to remove main rotor (M/R) rotating swashplates (swashplates) from service that have accumulated less than 7 years since the date of manufacture; increasing the life limit for certain swashplates; requiring additional visual inspections, and adding repetitive inspections for certain swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture; and updating the service information. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, the agency is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by September 12, 2022.

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

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

For service information identified in this SNPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *www.airbus.com/helicopters/technical-services/support.html.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0015; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, this SNPRM, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; phone: (202) 267–9167; email: *hal.jensen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0015; Project Identifier AD–2021–00832–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may again revise this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this SNPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this SNPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this SNPRM. Submissions containing CBI should be sent to Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone: (202) 267–9167; email: *hal.jensen@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model EC225LP helicopters, with an M/R swashplate part number (P/N) 332A31–3074–00 or P/N 332A31–3074–01 installed. The NPRM published in the **Federal Register** on January 26, 2022 (87 FR 3943). The NPRM proposed to supersede AD 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020) (AD 2020–23–05), which applies to certain Airbus Helicopters Model EC225LP helicopters. AD 2020–23–05 requires inspecting the swashplate control rod attachment yokes (yokes) of certain swashplates, establishing a life limit, performing a one-time inspection of stripped yokes, and applicable corrective actions. AD 2020–23–05 was prompted by a crack in a yoke, which could result in failure of the yoke, loss of M/R control, and subsequent loss of control of the helicopter. AD 2020–23–05 was also prompted by EASA AD 2019–0074, dated March 28, 2019 (EASA AD 2019–0074), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters (AH), formerly Eurocopter, Eurocopter France, Model EC 225 LP helicopters. EASA advised that Airbus Helicopters established a life limit (also called a service life limit) of 12 years for the swashplate and added a reporting requirement if there is a crack or corrosion in a yoke. EASA further advised that additional analysis determined that it is necessary to introduce a new life limit for the affected swashplates.

In the NPRM, the FAA proposed to retain all the requirements of AD 2020–23–05. The NPRM also proposed to include a revised compliance time for the initial visual inspection of the yokes

on swashplates that have accumulated less than seven years since the date of manufacture; and clarification that dye penetrant inspection of the yoke is required before further flight if no cracks are detected during the visual inspection.

The NPRM was prompted by the determination that a revised compliance time is necessary for swashplates that have accumulated less than seven years since the date of manufacture. The FAA has also determined that clarification is necessary regarding when it is necessary to do a dye penetrant inspection of the yoke.

Actions Since the NPRM Was Issued

Since the NPRM was issued, EASA issued EASA AD 2019–0074R1, dated March 8, 2022 (EASA AD 2019–0074R1), which supersedes EASA AD 2019–0074. EASA advises that additional investigation confirmed that the life limit of certain swashplates can be extended and Airbus Helicopters has issued updated service information to reflect the new life limit.

Also, since the NPRM was issued, the FAA determined that swashplates that have accumulated less than 7 years since the date of manufacture are not susceptible to the unsafe condition and should be removed from paragraph (g) of the proposed AD. The FAA also determined that paragraph (g) of the proposed AD needs to be revised to include repetitive inspections for swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture, and the criteria for when to perform a dye penetrant inspection needs to be revised.

The FAA determined there was an error in the Background section of the NPRM, which stated, ''AD 2020–23–05 was prompted by a crack in a swashplate yoke.'' The FAA determined AD 2020–23–05 was not prompted by a crack in a yoke, but was prompted by testing conducted by Airbus Helicopters, which determined cracks may develop overtime. The FAA also determined that the applicable service information required by the proposed AD needs to be revised in order to include the updated revision.

Finally, the FAA determined that the time estimated for inspecting the yokes needed to be increased from 0.25 work-hour to 0.50 work-hour, which increased the estimated cost for that inspection from $21 to $43 per helicopter per inspection cycle.

Comments

The following discussion presents the comments received on the NPRM and the FAA's response.

Request To Revise the Required Actions Paragraph of the Proposed AD

Five commenters requested the FAA revise the Required Actions paragraph of the proposed AD by removing the visual inspection for swashplates that have accumulated less than 7 years since the date of manufacture. Airbus Helicopters stated that testing was performed for certain aluminum alloys and as a result Airbus Helicopters defined a calendar threshold of 7 years, after which the swashplate may present crack initiation. Airbus Helicopters further explained due to this testing, there is no rationale to require the visual inspection prior to the 7 year threshold. An additional commenter stated the inspection for swashplates that have accumulated less than 7 years since the date of manufacture is not in line with the required service information. Additionally, Air Center Helicopters Inc., explained that the EASA AD and the service information do not require repetitive visual inspections for any swashplates that have accumulated less than 7 years since the date of manufacture and that these repetitive inspections are not required until after the swashplate has accumulated 7 or more years since the date of manufacture.

The FAA agrees and has revised the Required Actions paragraph of this proposed AD by removing the inspection requirements for swashplates that have accumulated less than 7 years since the date of manufacture.

Four commenters requested the FAA revise the Required Actions paragraph to include a repetitive visual inspection, at intervals not to exceed 15 hours time-in-service (TIS) or 7 days, after certain swashplates have accumulated 7 or more years since the date of manufacture. Three commenters also requested that the FAA revise the Required Actions paragraph of this proposed AD to require that this repetitive visual inspection be performed utilizing a bright light and 10X magnifying glass.

The FAA partially agrees. The FAA agrees to revise the Required Actions paragraph of this proposed AD to include a repetitive visual inspection, at intervals not to exceed 15 hours TIS or 7 days, whichever occurs first, for swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture, until the swashplate accumulates 13 years since the date of manufacture. The FAA disagrees with mandating the use of a bright light and 10X magnifying glass for this repetitive visual inspection because the FAA has not determined that a bright light or 10X magnifying glass are necessary for this repetitive visual inspection; however an operator may choose to use this inspection method.

Five commenters requested the FAA revise the Required Actions paragraph to remove the dye penetrant inspection in situations where no crack is detected. Airbus Helicopters stated with regards to crack detectability, the dye penetrant inspection creates an unnecessary burden if no crack is detected visually, and should only be performed if a scratch or surface degradation is detected. Two commenters also stated performing the dye penetrant inspection, if a crack is not detected, would increase the estimated costs and downtime for operators.

The FAA agrees to revise the Required Actions paragraph of this proposed AD to include an additional visual inspection for a scratch and surface degradation, if no crack is detected. The FAA determined if any indications of scratches or surface degradation are detected during the visual inspection, a dye penetrant inspection must be performed to address the unsafe condition. Accordingly, the FAA has revised the Required Actions paragraph to require a visual inspection for a scratch and surface degradation if no cracks are visually detected, and a dye penetrant inspection if there is any scratch or surface degradation.

Five commenters requested the FAA revise the Required Actions paragraph to extend the life limit of the swashplate from 12 years to 13 years, in accordance with the revised service information.

The FAA agrees and has revised the Required Actions paragraph of this proposed AD by increasing the life limit of the swashplate to 13 years.

Request To Use Latest Revision of the Applicable Service Information

Three commenters requested that the FAA revise the proposed AD to reference EASA AD 2019–0074R1 instead of EASA AD 2019–0074. The commenters also requested that the FAA revise the proposed AD to reference Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05A051, Revision 4, dated February 28, 2022 (EASB 05A051 Rev 4), instead of Airbus Helicopters EASB No. 05A051 and EASB No. 05A046, each Revision 2, and dated February 26, 2019.

The FAA agrees EASA AD 2019–0074R1 and EASB 05A051 Rev 4 are the appropriate sources of related information for the actions specified, and has revised this proposed AD to reference this updated information.

Request To Approve Future Revisions of the Service Information

Three commenters requested that the FAA revise the proposed AD to consider the accomplishment of future revisions of EASB 05A051 Rev 4 as acceptable for compliance with the proposed AD. Two commenters stated EASA AD 2019–0074R1 allows the use of future revisions of the applicable service information and requested that the FAA also allow compliance with later revisions. One commenter stated later revisions of the applicable service information should be allowed in order to capture future applicable appendixes, swashplate serial numbers, and swashplate manufacture dates.

The FAA disagrees with the request to allow future revisions of the applicable service information as acceptable for compliance with the proposed AD. Referring to documents that do not exist at the time the final rule is published violates Office of the Federal Register (OFR) regulations regarding approval of materials ''incorporated by reference'' in rules. These OFR regulations require that either the service document be submitted for approval by the OFR as ''referenced'' material, in which case it may be simply called out in the text of an AD, or the service document contents be published as part of the actual AD language. An AD may reference only the specific service document that was submitted and approved by the OFR for ''incorporation by reference.'' In order for operators to use later revisions of the referenced document (issued after the publication of the AD), either the FAA must revise the AD to reference the specific later revisions, or operators must request the approval of their use as an alternative method of compliance under the provisions of paragraph (j) of this proposed AD.

Request To Revise the Background Section of the Proposed AD

One commenter requested that the FAA revise the background section of the NPRM to indicate that no cracks to the swashplate have been detected in service, but testing by Airbus Helicopters determined that cracks could develop over time.

The FAA agrees with the commenter and has revised the Actions Since the NPRM was Issued section in this proposed AD accordingly.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after determining the unsafe condition described previously is likely to exist or develop in other helicopters of the same type design. Certain changes described above expand the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed one document that co-publishes two Airbus Helicopters EASB identification numbers: EASB 05A051 Rev 4 for Model EC225LP helicopters and EASB No. 05A046 for non-FAA type-certificated Model EC725AP helicopters, Revision 4, dated February 28, 2022 (EASB 05A046 Rev 4). This service information specifies inspections for swashplate P/N 332A31–3074–00 and P/N 332A31–3074–01. This service information specifies procedures for a repetitive inspection of the yokes for a crack and a one-time inspection of the stripped yokes for corrosion and a crack. If in doubt about whether there is a crack, this service information specifies performing a nondestructive inspection.

Additionally, this service information specifies touching up the swashplate with varnish if there is corrosion, removing any damage within allowable limits, and refinishing the yokes. If there is a crack in a yoke, this service information specifies replacing the swashplate. This service information also specifies a life limit of 13 years since the date of manufacture for the swashplates and reporting requirements if a crack or corrosion is discovered. EASB 05A051 Rev 4 also updates the list of serial numbers and manufacture dates of the swashplates. EASB 05A046 Rev 4, dated February 28, 2022, is not proposed for incorporation by reference in this SNPRM.

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

Proposed AD Requirements in This SNPRM

This proposed AD would retain some of the requirements of AD 2020–23–05. This proposed AD would also require compliance with a revised life limit, a repetitive visual inspection of the yokes on swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture; and if a crack is detected, removing the swashplate from service. If no cracks are detected but a scratch or surface degradation is detected, this proposed AD would require performing a dye penetrant inspection of the yoke. If a crack is detected during the dye penetrant inspection, this proposed AD would require removing the swashplate from service.

Differences Between This SNPRM and EASA AD 2019–0074R1 or the Service Information

EASB 05A051 Rev 4 requires performing a non-destructive inspection if in doubt about whether there is a crack in a yoke. This proposed AD would require a visual inspection and if no cracks are detected, visually inspecting for a scratch and surface degradation. If a scratch or surface degradation is detected, this proposed AD would require a non-destructive inspection (dye penetrant inspection). EASB 05A051 Rev 4 also specifies sending the swashplate back to Airbus Helicopters if cracks are found, whereas this proposed AD would not require sending any affected parts back to Airbus Helicopters.

EASA AD 2019–0074R1 specifies instructions for reporting inspection results, whereas this proposed AD would not require reporting inspection results.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 28 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determination of the manufacture date of the swashplate.	0.5 work-hour × $85 per hour = $43	$0	$43	$1,204.

ESTIMATED COSTS FOR REQUIRED ACTIONS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspecting the yokes	0.5 work-hour × $85 per hour = $43 per inspection cycle.	0	43 per inspection cycle.	1,204 per inspection cycle.
Removing grease, stripping the yokes, and inspecting the stripped yokes.	8 work-hours × $85 per hour = $680	0	680	19,040.
Creating a life limit record	1 work-hour × $85 per hour = $85	0	85	2,380.

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Removing any corrosion or repairing damage within the allowable limit.	3 work-hours × $85 per hour = $255	$0	$255
Replacing the swashplate	6 work-hours × $85 per hour = $510	85,661	86,171
Dye-penetrant inspection	6 work-hours × $85 per hour = $510	50	560

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020; and

■ b. Adding the following new airworthiness directive:

Airbus Helicopters: Docket No. FAA–2022–0015; Project Identifier AD–2021–00832–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by September 12, 2022.

(b) Affected ADs

This AD replaces AD 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020) (AD 2020–23–05).

(c) Applicability

This AD applies to Airbus Helicopters Model EC225LP helicopters, certificated in any category, with a main rotor (M/R) rotating swashplate (swashplate) part number (P/N) 332A31–3074–00 or P/N 332A31–3074–01 installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6230, Main Rotor Mast/Swashplate.

(e) Unsafe Condition

This AD was prompted by results of testing, which determined that a crack could develop in a swashplate control rod attachment yoke (yoke), and the notification of a new life limit for certain swashplates. The FAA is issuing this AD to detect and correct a crack in a yoke. The unsafe condition, if not addressed, could result in failure of the yoke, loss of M/R control, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Before further flight, review Appendix 4.A. of Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05A051, Revision 4, dated February 28, 2022 (EASB 05A051 Rev 4) to determine the date of manufacture of the swashplate.

(1) If the swashplate has accumulated 13 or more years since the date of manufacture, remove the swashplate from service.

(2) If the swashplate has accumulated less than 13 years since the date of manufacture, create a component history card or equivalent record indicating a life limit of 13 years since the date of manufacture. Thereafter, continue to record the life limit of the swashplate on its component history card or equivalent record and remove any

swashplate from service before accumulating 13 years since the date of manufacture.

(3) For each swashplate that has accumulated 7 or more years, but less than 13 years, since the date of manufacture, within 15 hours time-in-service (TIS) or 7 days, whichever occurs first after the effective date of this AD, and thereafter at intervals not to exceed 15 hours TIS or 7 days, whichever occurs first, until the swashplate accumulates 13 years since the date of manufacture, visually inspect each yoke for a crack, paying particular attention to the areas shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. If there is any crack on the yoke, before further flight, remove the swashplate from service.

(i) If no cracks are visually detected, before further flight, visually inspect for a scratch and surface degradation on the yoke.

(ii) If there is any scratch or surface degradation on the yoke, before further flight, perform a dye penetrant inspection of the yoke for a crack.

(iii) If there is any crack on the yoke, before further flight, remove the swashplate from service.

(4) For each swashplate that has accumulated 7 or more years, but less than 13 years, since the date of manufacture, within 100 hours TIS after the effective date of this AD:

(i) Remove the grease from areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. Using a plastic spatula, strip areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. Do not use a metal tool to strip any area of a yoke.

(ii) Inspect areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4 for corrosion, pitting, and loss of material.

(A) If there is any corrosion less than 0.0078 in. (0.2 mm), before further flight, remove the corrosion and apply varnish (Vernelec 43022 or equivalent) to the surface of areas (E), (F), (G), (H), (J), and (K).

(B) If there is any pitting or loss of material of less than 0.0078 in. (0.2 mm), before further flight, remove the damage by sanding with sandpaper 200/400 or 330.

(C) If there is any corrosion, pitting, or loss of material of 0.0078 in. (0.2 mm) or greater, before further flight, remove the swashplate from service.

(iii) Visually inspect each yoke for a crack, paying particular attention to the areas shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4.

(A) If there is any crack on the yoke, before further flight, remove the swashplate from service.

(B) If no cracks are visually detected, before further flight, perform the actions as required in paragraphs (g)(3)(i) through (iii) of this AD.

(h) Credit for Previous Actions

If you performed the actions in paragraph (g)(4) of this AD before the effective date of this AD using Airbus Helicopters EASB No. 05A051, Revision 1, dated November 16, 2017; Airbus Helicopters EASB No. 05A051, Revision 2, dated February 26, 2019; or Airbus Helicopters EASB No. 05A051 Revision 3, dated December 7, 2021, you have met the requirements of paragraph (g)(4) of this AD.

(i) Special Flight Permit

Special flight permits are prohibited.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

(1) For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone: (202) 267–9167; email: *hal.jensen@faa.gov.*

(2) For service information identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *www.airbus.com/helicopters/services/technical-support.html.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2019–0074R1, dated March 8, 2022. You may view the EASA AD at *www.regulations.gov* in Docket No. FAA–2022–0015.

Issued on July 22, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–16163 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0858; Airspace Docket No. 22–AEA–5]

RIN 2120–AA66

Proposed Establishment and Amendment of Area Navigation (RNAV) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Area Navigation (RNAV) route Q–141 and amend RNAV route Q–437 in support of the Northeast Corridor Atlantic Coast Route Project.

DATES: Comments must be received on or before September 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527 or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0858; Airspace Docket No. 22–AEA–5 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

Authority for This Rulemaking

SUPPLEMENTARY INFORMATION: The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the

safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it expands the availability of RNAV routes in the National Airspace System, increases airspace capacity, and reduces complexity in high air traffic volume areas.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0858; Airspace Docket No. 22–AEA–5) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0858; Airspace Docket No. 22–AEA–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, issued August 10. 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to establish RNAV route Q–141, and amend RNAV route Q–437 in the eastern United States in support of the Northeast Corridor Atlantic Coast Route project.

Q–141: Q–141 is a proposed new route that would extend from the HOUKY, VA waypoint (WP) (located in the vicinity of the Hopewell, VA (HPW), VOR and Tactical Air Navigational System (VORTAC)) to the NALES, DE, WP. Q–141 would expand the availability of RNAV routing in the area.

Q–437: Q–437 extends from the VILLS, NJ, Fix, (located northwest of the Sea Isle, NJ (SIE), VORTAC to the SLANG, VT, WP (located northeast of the Cambridge, NY (CAM), VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME)). The FAA proposes to terminate the route at the LLUND, NY, Fix (located north of the Kennedy, NY (JFK), VOR/DME). All points north of the LLUND Fix (*i.e.,* BINGS, WARUV, and SLANG) would be removed from the route. This is based on low demand for those segments and would better fit traffic flows in the area. Additionally, the LUIGI, NJ, Fix would be removed from the route description because it does not mark a turn point.

The proposed full route descriptions of Q–141 and Q–437 are listed in the amendments to part 71 set forth below.

United States Area Navigation Routes are published in paragraph 2006 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The routes listed in this document would be subsequently published in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR part 71 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021 and effective September 15, 2021, is amended as follows:

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–141 HOUKY, VA to NALES, DE [New]

HOUKY, VA	WP	(Lat. 37°19′55.98″ N, long. 077°07′57.63″ W)
TAPPA, VA	FIX	(Lat. 37°58′12.66″ N, long. 076°50′40.62″ W)
HYTRA, MD	WP	(Lat. 38°17′31.91″ N, long. 076°24′49.80″ W)
BLNTN, MD	WP	(Lat. 38°44′10.33″ N, long. 075°59′02.69″ W)
NALES, DE	FIX	(Lat. 38°53′35.20″ N, long. 075°38′11.13″ W)

* * * * *

Q–437 VILLS, NJ to LLUND, NY [Amended]

VILLS, NJ	FIX	(Lat. 39°18′03.87″ N, long. 075°06′37.90″ W)
DITCH, NJ	FIX	(Lat. 39°47′37.86″ N, long. 074°42′59.88″ W)
HNNAH, NJ	WP	(Lat. 40°28′12.73″ N, long. 074°02′36.62″ W)
LLUND, NY	FIX	(Lat. 40°51′45.04″ N, long. 073°46′57.30″ W)

* * * * *

Issued in Washington, DC, on July 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–16236 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0857; Airspace Docket No. 21–AEA–28]

RIN 2120–AA66

Proposed Amendment and Establishment of Area Navigation (RNAV) Routes; Northeast United States.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend one low altitude area navigation (RNAV) route (T-route), and establish four new T-routes in the northeast United States. The routes would augment the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) Program. The purpose is to enhance the efficiency of the National Airspace System (NAS) by transitioning from a ground-based to a satellite-based navigation system.

DATES: Comments must be received on or before September 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0857; Airspace Docket No. 21–AEA–28 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV routes in the northeast United States and improve the efficient flow of air traffic within the NAS by lessening the dependency on ground-based navigation.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0857; Airspace Docket No. 21–AEA–28) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0857; Airspace Docket No. 21–AEA–28.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through

the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend one low altitude RNAV T-route, and establish four T-routes in the northeast United States to augment the VOR MON Program.

T–356: T–356 extends from the WOOLY, MD, Fix to the ELUDE, MD, Fix. The FAA proposes to extend T–356 at both ends. The start point would be moved from the WOOLY Fix to the HOGZZ, MD, waypoint (WP). The HOGZZ WP is being renamed TWIRK, MD, WP. From the TWIRK WP, the route would proceed to the BRILA, MD, WP, then to the WOOLY, MD, Fix where T–356 would join the route as currently charted to the SWANN, MD, Fix. The GATBY, MD, Fix and the KERNO, MD, Fix would be removed from the route description. From the SWANN Fix, the route would go to the ODESA, MD, Fix. The ELUDE, MD, Fix would be removed from the description. After the ODESA Fix, T–356 would be extended northward to the WIGGZ, PA, WP (which will replace the Slate Run, PA (SLT), VOR and Tactical Air Navigational System (VORTAC)). The following points would be added after the ODESA Fix: APEER, MD,WP; REESY, PA, WP; FOLEZ, PA, WP; PIKKE, PA, WP; BOYER, PA, WP; Ravine, PA (RAV), VORTAC; Selinsgrove, PA (SEG), VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME); and the WIGGZ, PA, WP. T–356 would overlay airway V–170 from the PIKKE, PA, WP to the WIGGZ, PA, WP. As amended, T–356 would extend from the TWIRK, MD, WP to the WIGGZ, PA, WP.

The following are proposed new T routes:

T–448: T–448 would extend from the TOMYD, PA, WP to the FOLEZ, PA, WP. The TOMYD WP is being moved 2.8 NM north of its current location. T–448 would serve as a replacement for a portion of airway V–408 (but not an exact overlay).

T–451: T–451 would extend from the ROBRT, MD, Fix to the ELIOT, PA, Fix. It would overlay a portion of airway V–39 from the ROBRT WP to the ELIOT WP. The HEXSN, PA, WP is used in the route description in place of the Lancaster, PA (LRP), VOR/DME.

T–453: T–453 would extend from the VINNY, PA, Fix to the PARKE, NJ, WP. T–453 would overlay airway V–457 from the VINNY Fix to the PARKE WP.

T–460: T–460 would extend from the Philipsburg, PA (PSB), VORTAC to the GLYDE, MA, Fix. It would overlay a portion of airway V–576 from Philipsburg to the ARRKK, NY, WP; and airway V–292 from the ARRKK WP to the GLYDE, MA, WP.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The routes listed in this document would be subsequently published in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR part 71 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–356 TWIRK, MD to WIGGZ, PA [Amended]		
TWIRK, MD	WP	(Lat. 39°34′36.70″ N, long. 077°12′44.75″ W)
BRILA, MD	WP	(Lat. 39°23′53.04″ N, long. 077°08′31.89″ W)
WOOLY, MD	FIX	(Lat. 39°20′19.18″ N, long. 077°02′11.17″ W)
DROSA, MD	WP	(Lat. 39°18′30.32″ N, long. 076°58′06.22″ W)
OBWON, MD	WP	(Lat. 39°11′54.69″ N, long. 076°32′04.84″ W)
SWANN, MD	FIX	(Lat. 39°09′05.28″ N, long. 076°13′43.94″ W)
ODESA, MD	FIX	(Lat. 39°29′29.00″ N, long. 075°49′44.37″ W)
APEER, MD	WP	(Lat. 39°37′32.94″ N, long. 075°50′25.39″ W)

REESY, PA	WP	(Lat. 39°45′27.94″ N, long. 075°52′07.09″ W)
FOLEZ, PA	WP	(Lat. 39°55′32.76″ N, long. 075°49′16.49″ W)
PIKKE, PA	WP	(Lat. 40°05′27.21″ N, long. 075°52′12.11″ W)
BOYER, PA	FIX	(Lat. 40°16′36.84″ N, long. 076°05′09.38″ W)
Ravine, PA (RAV)	VORTAC	(Lat. 40°33′12.21″ N, long. 076°35′57.77″ W)
Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
WIGGZ, PA	WP	(Lat. 41°30′51.00″ N, long. 077°58′52.00″ W)

* * * * * * *

T–448 TOMYD, PA to FOLEZ, PA [New]

TOMYD, PA	WP	(Lat. 39°43′39.02″ N, long. 077°07′58.89″ W)
KIRMT, PA	WP	(Lat. 39°46′33.26″ N, long. 076°11′46.75″ W)
GLOMO, PA	WP	(Lat. 39°51′54.76″ N, long. 075°58′45.22″ W)
FOLEZ, PA	WP	(Lat. 39°55′32.76″ N, long. 075°49′16.49″ W)

* * * * * * *

T–451 ROBRT, MD to ELIOT, PA [New]

ROBRT, MD	FIX	(Lat. 39°36′57.77″ N, long. 077°22′04.55″ W)
HEXSN, PA	LWP	(Lat. 40°07′12.46″ N, long. 076°17′28.38″ W)
East Texas, PA (ETX)	VOR/DME	(Lat. 40°34′51.74″ N, long. 075°41′02.51″ W)
ELIOT, PA	FIX	(Lat. 40°49′06.65″ N, long. 075°07′48.43″ W)

* * * * * * *

T–453 VINNY, PA to PARKE, NJ [New]

VINNY, PA	FIX	(Lat. 39°45′16.64″ N, long. 076°36′30.16″ W)
HEXSN, PA	WP	(Lat. 40°07′12.46″ N, long. 076°17′28.38″ W)
PARKE, NJ	WP	(Lat. 40°40′59.46″ N, long. 075°04′35.32″ W)

* * * * * * *

T–460 Philipsburg, PA (PSB) to GLYDE, MA [New]

Philipsburg, PA (PSB)	VORTAC	(Lat. 40°54′58.53″ N, long. 077°59′33.78″ W)
LYKOM, PA	WP	(Lat. 41°20′18.75″ N, long. 076°46′30.30″ W)
ARRKK, NY	WP	(Lat. 42°03′48.52″ N, long. 075°19′00.41″ W)
SAGES, NY	FIX	(Lat. 42°02′46.33″ N, long. 074°19′10.33″ W)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09′43.05″ N, long. 072°42′58.32″ W)
GLYDE, MA	FIX	(Lat. 42°16′03.84″ N, long. 071°48′42.76″ W)

* * * * *

Issued in Washington, DC, on July 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–16235 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

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

RIN 2120–AA66

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

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

ACTION: Notice of proposed rulemaking (NPRM).

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

DATES: Comments must be received on or before September 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. DOT, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify ''FAA Docket No. FAA–2022–0711; Airspace Docket No. 21–ANM–64,'' at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related

aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0711; Airspace Docket No. 21–ANM–64.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

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

The Class E airspace designated as a surface area should be expanded to more appropriately contain circling maneuvers.

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

The Class E airspace extending upward from 1,200 feet above the surface should be removed, as this area is already contained within the Denver en route domestic airspace area, and duplication is not necessary.

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

Class E2 and E5 airspace designations are published in paragraphs 6002 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11, which is published yearly and becomes effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM CO E2 Akron, CO [Amended]

Colorado Plains Regional Airport, CO

(Lat. 40°10′32″ N, long. 103°13′19″ W)

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

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

* * * * *

ANM CO E5 Akron, CO [Amended]

Colorado Plains Regional Airport, CO

(Lat. 40°10′32″ N, long. 103°13′19″ W)

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

Issued in Des Moines, Washington, on July 19, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–16222 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0764; Airspace Docket No. 21–ANM–37]

RIN 2120–AA66

Proposed Amendment of Class D and Class E Airspace; Bozeman Yellowstone International Airport, MT

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class D and E surface areas, the Class E airspace area designated as an extension to a Class D or Class E surface area, and the Class E airspace extending upward from 700 feet above the surface at Bozeman Yellowstone International Airport, MT. Additionally, this action proposes several administrative amendments to update the airport's legal descriptions. These actions will ensure the safety and management of instrument flight rules (IFR) and visual flight rules (VFR) operations at the airport.

DATES: Comments must be received on or before September 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0764; Airspace Docket No. 21–ANM–37, at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0764; Airspace Docket No. 21–ANM–37.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by modifying Class D and Class E surface areas, the Class E airspace area designated as an extension to a Class D or Class E surface area, the Class E airspace extending upward from 700 feet above the surface, and the Class E airspace designated as en route domestic airspace area at Bozeman Yellowstone International Airport, MT.

Class D airspace is intended to contain IFR arrival operations while between the surface and 1,000 feet above the surface, and IFR departure operations while between the surface and the base of adjacent controlled airspace. The current Class D airspace radius is 5.4 miles, which is excessive. This radius should be reduced to 4.9 miles, as additional airspace is not necessary. The Class D airspace should be expanded to the southeast of the airport due to rising terrain, as it's needed to contain departures until reaching 700 feet above the surface.

The Class E surface airspace should be amended to be coincident with the

Bozeman Yellowstone International Airport's Class D airspace legal description.

The Class E airspace area designated as an extension to a Class D or Class E surface area should be removed southwest of the airport, as it is no longer needed. The Class E airspace area designated as an extension to a Class D or Class E surface area northwest of the airport should be modified to more appropriately contain arrivals on the ILS/LOC RWY 12 approach.

The Class E airspace extending upward from 700 feet above the surface around Bozeman Yellowstone International Airport should be reduced from a 13.5-mile radius to a 6.9-mile radius around the airport, as additional airspace is not necessary to contain IFR departures flying toward or over rising terrain. The Class E airspace extending upward from 700 feet above the surface northwest of the airport should be reduced, as the existing airspace is excessive and not necessary. Class E airspace extending upward from 700 feet above the surface should be extended southeast of the airport to contain IFR departures until reaching 1,200 feet above the surface, and IFR arrivals descending below 1,500 feet above the surface.

Finally, the FAA proposes several administrative modifications to the airport's legal descriptions. The Bozeman Yellowstone International Airport geographic coordinates in the Class D and Class E legal descriptions should be updated to match the FAA's database. The Class D and Class E2 legal descriptions should also be updated to replace the outdated use of the phrases ''Notice to Airmen,'' and ''Airport/Facility Directory.'' These phrases should be amended to read ''Notice to Air Missions'' and ''Chart Supplement,'' respectively, to align with the FAA's current nomenclature.

Class D, E2, E4, E5, and E6 airspace designations are published in paragraphs 5000, 6002, 6004, 6005, and 6006, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM MT D Bozeman, MT [Amended]

Bozeman Yellowstone International Airport, MT
(Lat. 45°46′38″ N, long. 111°09′01″ W)

That airspace extending upward from the surface to and including 7,000 feet MSL within a 4.9-mile radius of Bozeman Yellowstone International Airport, and within 2.0 miles each side of the 146° bearing from the airport extending from the 4.9-mile radius of the airport to 6.5 miles southeast of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

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

* * * * *

ANM MT E2 Bozeman, MT [Amended]

Bozeman Yellowstone International Airport, MT
(Lat. 45°46′38″ N, long. 111°09′01″ W)

That airspace extending upward from the surface within a 4.9-mile radius of Bozeman Yellowstone International Airport, and within 2.0 miles each side of the 146° bearing from the airport extending from the 4.9-mile radius of the airport to 6.5 miles southeast of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E.

* * * * *

ANM MT E4 Bozeman, MT [Amended]

Bozeman Yellowstone International Airport, MT
(Lat. 45°46′38″ N, long. 111°09′01″ W)

That airspace extending upward from the surface within 3.4 miles each side of the 316° bearing from the Bozeman Yellowstone International Airport extending from the 4.9-mile radius of the airport to 13.5 miles northwest of the airport.

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

* * * * *

ANM MT E5 Bozeman, MT [Amended]

Bozeman Yellowstone International Airport, MT
(Lat. 45°46′38″ N, long. 111°09′01″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius from the Bozeman Yellowstone International Airport, and within 1.8 miles each side of the 131° bearing from the airport extending from the 6.9-mile radius to 14.3 miles southeast of the airport, and within 2.7 miles northeast and 2.9 miles southwest of the 155° bearing from the airport extending from the 6.9-mile radius to 10.6 miles southeast of the airport, and within 3.6 miles each side of the 316° bearing from the airport extending from the 6.9-mile radius to 15.5 miles northwest of the airport.

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

ANM MT E6 Bozeman, MT [Amended]

Bozeman Yellowstone International Airport, MT

(Lat. 45°46′38″ N, long. 111°09′01″ W)

That airspace extending upward from 1,200 feet above the surface within a 50-mile radius of the Bozeman Yellowstone International Airport, excluding existing lateral limits of controlled airspace 12,000 feet MSL and above.

Issued in Des Moines, Washington, on July 19, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–16221 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR 153

[Docket No. RM22–21–000]

Petition for Rulemaking

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notification of petition for rulemaking.

SUMMARY: Take notice that, on July 22, 2022, WWALS Watershed Coalition, Inc., LEAD Agency, Inc., Kissimmee Waterkeeper, Our Santa Fe River, Center for a Sustainable Coast, Three Rivers Waterkeeper, and Lumber Riverkeeper (collectively, Petitioners), pursuant to the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, filed a petition requesting that the Commission conduct a rulemaking to revisit, consider, and modify the Commission's former decisions about inland liquefied natural gas (LNG) export facilities to require all LNG export facilities to be under Commission oversight.

DATES: Petition filed on July 22, 2022. Comments are due by 5 p.m. Eastern time on September 20, 2022.

ADDRESSES: Any person that wishes to comment in this proceeding must file comments in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211. Comments will be considered by the Commission in determining the appropriate action to be taken. Comments must be filed on or before the comment date. The Commission strongly encourages electronic filings of comments in lieu of paper using the ''eFile'' link at *https://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Vinnik, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Ph 202–502–6460, *Daniel.vinnik@ferc.gov.*

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*https://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020.

Dated: July 22, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16219 Filed 7–28–22; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB–2022–0007; Notice No. 213]

RIN 1513–AC88

Proposed Addition of American Single Malt Whisky to the Standards of Identity for Distilled Spirits

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to amend the regulations that set forth the standards of identity for distilled spirits to include ''American single malt whisky'' as a type of whisky that is a distinctive product of the United States. This proposal follows petitions and comments submitted by several distillers and the American Single Malt Whisky Commission. TTB invites comments on this proposed amendment to its regulations.

DATES: Comments must be received on or before September 27, 2022.

ADDRESSES: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it within Docket No. TTB–2022–0007 as posted at *https://www.regulations.gov.* A direct link to that docket is available on the TTB website at *https://www.ttb.gov/distilled-spirits/notices-of-proposed-rulemaking* under Notice No. 213. Alternatively, you may submit comments via postal mail to the Director, Regulations and Ruling Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005. Please see the Public Participation section of this document for further information on the comments requested regarding this proposal and on the submission, confidentiality, and public disclosure of comments.

FOR FURTHER INFORMATION CONTACT: Christopher M. Thiemann, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone 202–453–2265.

SUPPLEMENTARY INFORMATION:

Background on the Labeling of Distilled Spirits

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers regulations regarding the labeling of distilled spirits that include setting forth ''standards of identity.'' The authority to establish these standards is based on section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e). That section authorizes the Secretary of the Treasury (the Secretary) to prescribe regulations relating to the ''packaging, marking, branding, and labeling and size and fill'' of alcohol beverage containers ''as will prohibit deception of the consumer with respect to such products'' and ''as will provide consumers with adequate information as to the identity and quality of the products * * *.'' Section 105(e) of the FAA Act also generally requires bottlers and importers of alcohol beverages to obtain certificates of label approval (COLAs) prior to bottling or importing alcohol beverages for sale in interstate commerce.

TTB administers these FAA Act provisions pursuant to section 1111(d)

of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). In addition, the Secretary has delegated certain administrative and enforcement authorities to TTB through Treasury Department Order 120–01.

Part 5 of title 27 of the Code of Federal Regulations (27 CFR part 5) sets forth the regulations implementing those provisions of section 105(e) of the FAA Act as they pertain to distilled spirits.

Classes and Types of Spirits

Subpart I of part 5 of the TTB regulations (27 CFR part 5) establishes standards of identity for distilled spirits products and categorizes these products according to various classes and types. As used in § 5.141, the term ''class'' refers to a general category of spirits. Currently, there are 12 different classes of distilled spirits set out in §§ 5.142–5.156, such as whisky, rum, gin, and brandy. As used in § 5.141, the term ''type'' refers to a subcategory within a class of spirits. For example, ''Cognac'' and ''fruit brandy'' are types of brandy, and ''Cachaça'' is a type of rum.

The TTB labeling regulations at 27 CFR 5.63(a)(2) require that the class and type of distilled spirits appear on the product's label. These regulations provide that the class and type must be stated in conformity with Part 5, Subpart I of the TTB regulations.

Classification of Malt Whisky

Section 5.143(a) sets forth the standard of identity for whisky as follows:

> (a) The *class whisky.* ''Whisky'' or ''whiskey'' is distilled spirits that is an alcoholic distillate from a fermented mash of any grain distilled at less than 95 percent alcohol by volume (190° proof) having the taste, aroma, and characteristics generally attributed to whisky, stored in oak barrels (except that corn whisky need not be so stored), and bottled at not less than 40 percent alcohol by volume (80° proof), and also includes mixtures of such distillates for which no specific standards of identity are prescribed.

In § 5.143, paragraphs (c)(1) through (18) categorize the specific types of whisky, such as Bourbon whisky, spirit whisky, and Scotch whisky. Currently, ''malt whisky'' is found in paragraph (c)(2) and is described as whisky produced at not more than 160° proof from a fermented mash of not less than 51 percent malted barley and stored at not more than 125° proof in charred new oak barrels. Such whisky stored in charred new oak barrels for a period of 2 years or more may optionally be further designated as ''straight.'' See 27 CFR 5.143(c)(5). Paragraph (c)(7) sets forth the standard for whisky distilled from malt mash, which is whisky produced in the United States at not exceeding 160° proof from a fermented mash of not less than 51 percent malted barley and stored in used oak barrels. As a result, the labeling regulations provide standards for identifying whisky as ''malt whisky'' and ''whisky distilled from malt mash'' but do not further specify standards for ''single malt whisky.''

Section 5.154(a)(3) provides that geographical names that are not names for distinctive types of distilled spirits, and that have not become generic, may not be used unless the product is produced in the particular place or region indicated in the name. Accordingly, a product designated as ''American whisky'' (or ''American single malt whisky'') must have been produced in the United States.

American Single Malt Whisky Petitions and Comments

Petitions

In October 2017, TTB received three petitions with similar content from XO Alambic, Rémy Cointreau, and Westland Distillery. Each of these petitioners noted that they were filing the petition on behalf of, or with, the American Single Malt Whiskey Commission (ASMWC), an association of at least seventy-five producers of whisky in the United States.

In their petitions, the distillers requested the establishment of a standard of identity to define the ''American single malt whisky'' category for producers and consumers alike. They noted that the American whisky category has been growing over the past decade and continues to expand, and that recognition of American single malt whisky is at an all-time high, with U.S. distillers winning international competitions with products in these categories. They stated that establishment of a standard of identity would benefit consumers, as it would provide a definition for the product, establish trust in the category, clarify label declarations, and equip consumers with the necessary information to make informed decisions so they can have confidence in the products they are choosing to buy in a similar way that Scotch whisky standards provide such information to American consumer. They also believe establishment of a standard of identity would strengthen the U.S. economy by increasing tax revenue related to the sale of American Single Malt Whiskey, and by creating jobs related to producing, distributing, and selling such a product and the ingredients used in this product.

With some slight, non-substantive variations, these petitions requested that TTB add a standard of identity as follows:

> American Single Malt Whisky is whisky that is mashed, matured and distilled at a single United States distillery, is so distilled to a proof not exceeding 160° proof from a fermented mash of 100% malted barley, is stored in oak containers not exceeding a capacity of 700 liters, and is bottled at not less than 80° proof.

The petitioners conveyed that they believe the proposed language is complementary to the long-standing regulatory definitions for whiskies such as bourbon, but is distinctive enough to add value to the new designation while not inhibiting innovation among producers of American Single Malt Whisky.

TTB's Rulemaking on Modernizing Its Labeling Regulations

On November 26, 2018, TTB published in the **Federal Register** a Notice of Proposed Rulemaking (Notice No. 176, 83 FR 60562) proposing to amend its regulations governing the labeling and advertising of wine, distilled spirits, and malt beverages to reorganize and recodify these regulations. TTB undertook this action in order to simplify and clarify its regulatory standards, incorporate guidance documents and current policy into the regulations, and reduce the regulatory burden on industry members where possible. In Notice No. 176, TTB sought comments from the public on the regulatory proposals and TTB received over 1,100 comments.

TTB did not include a standard of identity for American single malt whisky in the regulatory amendments proposed in Notice No. 176. Regardless, TTB received over 200 comments in support of a new standard for American single malt whisky, including one from the ASMWC, which was mirrored in a number of other comments, urging TTB to add such a standard. The ASMWC's comment in response to Notice No. 176 proposed a standard slightly modified from the original petitioned-for standard. This new proposal would require that the distillation, mashing, and maturation of American Single Malt Whisky take place in the United States, but would require only that the distillation take place at a single United States distillery. The ASMWC stated in their comment that it has the support of more than 130 producers of single malt whisky. They restated their view that the proposed language is complementary to existing definitions

for bourbon whisky and whisky, but distinctive enough to add value to the new designation while not inhibiting innovation among producers of American Single Malt Whisky.

On February 9, 2022, TTB published T.D. TTB–176, which finalized the updates to the regulations proposed in Notice No. 176 with regard to distilled spirits and malt beverages. TTB did not finalize a standard for American single malt whisky in that final rule because TTB had not yet published such a standard in a notice of proposed rulemaking.

TTB Regulatory Proposal

After reviewing the petitions and comments, the regulations on the standards of identity in 27 CFR part 5, and TTB's database of approved Certificates of Label Approval (COLAs) (as discussed below), TTB has determined that amending the standards of identity regulations at § 5.143 to provide for a new standard of identity for American Single Malt Whisky merits consideration and public comment, as invited in this notice of proposed rulemaking.

Therefore, this document proposes to amend the standard of identity in § 5.143(c) by adding American Single Malt Whisky as a type of whisky in paragraph (15), generally incorporating the proposal in the comments to Notice No. 176. Of note, TTB is proposing that American Single Malt Whisky could be stored in any oak barrel (used, uncharred new, or charred new) not exceeding 700 liters, as the petitioners requested.

Effect on Currently Approved Labels

If finalized, this amendment to the TTB regulations would revoke by operation of regulation any COLA that uses the term ''American single malt whisky'' as a designation for a distilled spirits product that does not meet the proposed standard of identity. TTB has searched its COLA database and does not believe that this rulemaking will affect any existing labels. To minimize the adverse effect on industry members who hold COLAs for labels that conflict with the proposed ''American single malt whisky'' designation and that would therefore be revoked by operation of regulation, however, TTB could allow for a time-limited use up of such labels by delaying the effective date of the rule establishing this designation. Additionally, TTB specifically seeks comments on the impact on current producers, including whether this rulemaking would affect any existing labels. TTB notes that distillers currently using the designations ''malt whisky,'' ''American malt whisky,'' ''whisky distilled from malt mash,'' or ''American whisky distilled from malt mash'' on their labels may continue to do so.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on this proposed rule, including on whether the proposed amendment would have an adverse impact on owners of U.S. trademarks and current producers of malt whisky. In addition, TTB specifically seeks comments on the following questions:

- Noting that other whisky standards do not incorporate size restrictions for barrels, is a 700-liter limit for oak barrels for aging American single malt whisky necessary or appropriate?
- What impact, if any, would this new standard of identity have on current producers of malt whisky?
- If TTB adopts this proposed amendment, and if any previously approved labels are impacted, for how long should TTB allow the use of previously approved labels for American single malt whisky that do not meet the new standard of identity before they are revoked by operation of regulation?
- Is it appropriate that the new standard of identity allows the use of used, uncharred new, and charred new oak barrels?
- Should TTB amend its regulations to allow for the designation ''straight'' to be used with American Single Malt Whisky?
- Should the use of coloring, flavoring, or blending materials be allowed in the production of American single malt whisky? If so, what coloring, flavoring, or blending materials are ''customarily employed'' in the production of American single malt whisky, in accordance with 27 CFR 5.155? Please provide any available evidence of their use.
- Should TTB amend its regulations to allow for mixtures of American single malt whisky to be labeled as ''blended American single malt whisky,'' similar to how TTB regulations allow for blended Scotch whisky and blended Canadian whisky to be labeled, respectively, ''blended Scotch whisky'' and ''blended Canadian whisky''?
- On February 9, 2022, the Department of the Treasury released a report, ''Competition in the Markets for Beer, Wine, and Spirits,'' which was produced in response to Executive Order 14036, ''Promoting Competition in the American Economy'' (86 FR 36987, July 9, 2021). Would the addition of a standard of identity for American Single Malt Whisky affect competition in the alcohol beverage market?

Submitting Comments

You may submit comments on this proposal as an individual or on behalf of a business or other organization via the *Regulations.gov* website or via postal mail, as described in the **ADDRESSES** section of this document. Your comment must reference Notice No. 213 and must be submitted or postmarked by the closing date shown in the **DATES** section of this document. You may upload or include attachments with your comment. You also may submit a comment requesting a public hearing on this proposal. The TTB Administrator reserves the right to determine whether to hold a public hearing. If TTB schedules a public hearing, it will publish a notice of the date, time, and place for the hearing in the **Federal Register**.

Confidentiality and Disclosure of Comments

All submitted comments and attachments are part of the rulemaking record and are subject to public disclosure. Do not enclose any material in your comments that you consider confidential or that is inappropriate for disclosure.

TTB will post, and you may view, copies of this document, its supporting materials, and any comments TTB receives about this proposal within the related *Regulations.gov* docket. In general, TTB will post comments as submitted, and it will not redact any identifying or contact information from the body of a comment or attachment.

Please contact TTB's Regulations and Rulings division by email using the web form available at *https://www.ttb.gov/contact-rrd,* or by telephone at 202–453–2265, if you have any questions regarding how to comment on this proposal or to request copies of this document, its supporting materials, or the comments received in response.

Regulatory Analysis and Notices

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), TTB certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed rule only adds a new standard of identity for whisky at 27 CFR 5.143, which allows for the designation of a new class and type designation on labels, and it imposes no new reporting, recordkeeping, or other

administrative requirements. TTB searched the COLAs Online database and did not find any labels that we believe would be affected, but we are taking public comment on the issue of affected labels to get more information about the potential economic effects of the rulemaking. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Christopher M. Thiemann of the Regulations and Rulings Division drafted this notice of proposed rulemaking.

List of Subjects in 27 CFR Part 5

Advertising, Alcohol and alcoholic beverages, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, Packaging and containers, and Reporting and recordkeeping requirements.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, TTB proposes to amend title 27, chapter I, part 5, Code of Federal Regulations, as follows:

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205 and 207.

Subpart C—Standards of Identity for Distilled Spirits

■ 2. Section 5.143 is amended by:

■ a. Adding a sentence at the end of paragraph (b); and

■ b. In Table 1 to paragraph (c), adding paragraph (15).

The additions read as follows:

§ 5.143 Whisky.

* * * * *

(b) * * * ''American single malt whisky'' must be distilled entirely at one U.S. distillery, and must be mashed, distilled, and aged in the United States.

(c) * * *

TABLE 1 TO PARAGRAPH (c)—TYPES OF WHISKY AND PRODUCTION, STORAGE, AND PROCESSING STANDARDS

Type	Source	Distillation proof	Storage	Neutral spirits permitted	Allowable coloring, flavoring, blending materials permitted
*	*	*	*	*	*
(15) American single malt whisky.	Fermented mash of 100 percent malted barley.	160° or less ...	Oak barrels not exceeding 700 liters.	No	Yes.

* * * * *

Signed: July 20, 2022.

Mary G. Ryan,

Administrator.

Approved: July 20, 2022.

Thomas C. West, Jr.,

Deputy Assistant Secretary (Tax Policy).

[FR Doc. 2022–16244 Filed 7–28–22; 8:45 am]

BILLING CODE 4810–31–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR part 52

[EPA–R09–OAR–2022–0420; FRL–9970–01–R9]

Limited Approval and Limited Disapproval of California Air Plan Revisions; San Joaquin Valley Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a limited approval and limited disapproval of revisions to the San Joaquin Valley Air Pollution Control District (SJVAPCD or ''District'') portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compounds (VOC), oxides of nitrogen (NO_X), particulate matter (PM) (including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10})), and their precursors. This action addresses a revised rule governing the issuance of permits for stationary sources, focusing on the preconstruction review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA or ''Act''). We are taking comments on this proposal and a final action will follow.

DATES: Written comments must be received on or before August 29, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0420 at *www.regulations*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI and multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region IX, 75 Hawthorne St., San Francisco, CA

94105. By phone: (415) 972–3534, or by email at *yannayon.laura@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal including the date it was adopted by the District and submitted to the EPA by the California Air Resources Board (CARB), which is the governor's designee for California SIP submittals. This rule constitutes part of the SJVAPCD's program for preconstruction review and permitting of new or modified stationary sources under its jurisdiction. The rule revisions that are the subject of this action represent an update to the SJVAPCD's preconstruction review and permitting program and are intended to satisfy the requirements under part D of title I of the Act, ''nonattainment new source review (''NNSR'') as well as the general preconstruction review requirements under section 110(a)(2)(C) of the Act, minor new source review (''NSR'').

TABLE 1—SUBMITTED RULE

Rule No.	Rule title	Adopted	Submitted
Rule 2201	New and Modified Stationary Source Review Rule	08/15/19	11/20/19 [1]

On May 7, 2020, the submittal for Rule 2201 was found to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.[2]

B. Are there other versions of this rule?

Rule 2201 was previously approved into the California SIP on September 17, 2014.[3] If the EPA finalizes the action proposed herein, this prior version of the rule will be replaced in the SIP by the submitted rule identified in Table 1.

C. What is the purpose of the submitted rule?

As noted above and described in further detail below, the submitted rule is intended to satisfy the minor NSR and NNSR requirements of section 110(a)(2)(C) and part D of title I of the Act, and related EPA regulations. Minor NSR requirements are generally applicable for SIPs in all areas, while NNSR requirements apply only for areas designated as nonattainment for one or more National Ambient Air Quality Standards (NAAQS). The San Joaquin Valley is currently designated ''Extreme'' nonattainment for the 1997, 2008 and 2015 ozone NAAQS and ''Serious'' nonattainment for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS. See 40 CFR 81.305. Therefore, the designation of San Joaquin Valley as federal ozone and $PM_{2.5}$ nonattainment areas triggered the requirement for the District to develop and submit an NNSR program to the EPA for approval into the California SIP.

The EPA issued a final rule on December 6, 2018, that found that the District had failed to submit a SIP submittal addressing NNSR requirements for $PM_{2.5}$.[4] This finding of failure to submit triggered sanctions clocks under CAA section 179. The EPA's May 7, 2020 finding of completeness represented the EPA's determination that the District had corrected the deficiencies related to NNSR requirements for the 2006 and 2012 $PM_{2.5}$ NAAQS that formed the basis for the EPA's December 6, 2018 finding of failure to submit, and as a result, the associated sanctions and running of the sanctions clocks were permanently stopped.[5] The EPA's Technical Support Document (TSD) has more information about the purpose of the submitted rule.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

The EPA has evaluated Rule 2201 for compliance with the applicable requirements of section 110(a)(2)(C) and part D of title I of the CAA and the associated regulations at 40 CFR 51.160–165, consistent with the District's classification as an Extreme ozone nonattainment area and Serious $PM_{2.5}$ nonattainment area. We have also considered whether the rule meets the federal visibility requirements related to state NNSR programs as described in 40 CFR 51.307. Additionally, we have reviewed the rule for consistency with other CAA general requirements for SIP submittals, including requirements at section 110(a)(2) regarding rule enforceability, and requirements at sections 110(l) and 193 for SIP revisions.

Part D and title I of the CAA and the implementing regulations at 40 CFR 51.165 contain the NNSR program requirements for major stationary sources and major modifications for the pollutants for which the area has been designated nonattainment. The applicable provisions of 40 CFR 51.307 establish requirements for state NNSR programs to provide for review of major stationary sources and major modifications that may have an impact on visibility in any mandatory Class I Federal area, consistent with CAA section 169A. Section 110(a)(2)(A) of the Act requires that regulations submitted to the EPA for SIP approval must be clear and legally enforceable. Section 110(l) of the Act prohibits the EPA from approving SIP revisions that would interfere with any applicable requirement concerning attainment and reasonable further progress (RFP) or any other applicable requirement of the CAA. Section 193 of the Act prohibits the modification of a SIP-approved control requirement in effect before November 15, 1990, in a nonattainment area, unless the modification ensures equivalent or greater emission reductions of the relevant pollutant(s). With respect to procedures, CAA sections 110(a) and 110(l) require that a state conduct reasonable notice and hearing before adopting a SIP revision.

[1] The submittal was transmitted to the EPA via a letter from CARB dated November 15, 2019.

[2] See letter dated May 7, 2020, from Elizabeth J. Adams, U.S. EPA Region 9, to Richard Corey, CARB, regarding the November 20, 2019, submittal of District Rule 2201.

[3] 79 FR 55637.

[4] 83 FR 62720.

[5] See 40 CFR 52.31(d)(5).

B. Does the rule meet the evaluation criteria?

With the exceptions noted below, the EPA finds that Rule 2201 generally satisfies the applicable CAA and regulatory requirements for sources subject to NNSR permit program requirements for Extreme ozone nonattainment areas and Serious $PM_{2.5}$ nonattainment areas. Although the rule does not satisfy the related visibility requirements in 40 CFR 51.307, the San Joaquin Valley is subject to a Federal Implementation Plan that addresses these requirements.[6]

Rule 2201 complies with the substantive and procedural requirements of CAA section 110(l). With respect to the procedural requirements, based on our review of the public process documentation included with the submitted rules, we find that the SJVAPCD has provided sufficient evidence of public notice and opportunity for comment and public hearings prior to submittal of this SIP revision and has satisfied these procedural requirements under CAA section 110(l). With respect to the substantive requirements of CAA section 110(l), we have determined that our approval of Rule 2201 would not interfere with the area's ability to attain or maintain the NAAQS or with any other applicable requirements of the CAA.

Similarly, we find that Rule 2201 is approvable under section 193 of the Act because it does not modify any control requirement in effect before November 15, 1990.

Rule 2201 is generally consistent with criteria for the EPA's approval of regulations submitted for inclusion in the SIP, including the requirement in CAA section 110(a)(2)(A) that submitted regulations be clear and legally enforceable.

For the reasons stated above and explained further in our technical support document (TSD), we find that the submitted rule generally satisfies the applicable CAA and regulatory requirements for minor NSR and NNSR permit programs under CAA section 110(a)(2)(C) and part D of title I of the Act and other applicable requirements, subject to the exceptions noted below where the EPA has identified deficiencies. Because Rule 2201 is not fully consistent with these requirements, we are proposing a limited approval and limited disapproval of Rule 2201 under CAA sections 110(k)(3) and 301(a). Rule 2201 provisions that do not meet the evaluation criteria are summarized in the following section and described in more detail in the TSD included in the docket for this proposed action.

C. What are the rule deficiencies?

The following provisions of Rule 2201 do not satisfy the requirements of section 110 and/or part D of title I of the Act, and prevent full approval of the Rule 2201:

1. Definitions

Section 3.18 of Rule 2201 incorporates the federal definition of ''major modification'' through the definition of ''Federal Major Modification,'' but omits several other definitions necessary for proper application of this term and related calculation provisions. These missing definitions are listed in the TSD for this proposed rulemaking. The District must either include definitions for these terms, or explicitly state that for the purposes of the Rule 2201 definition of ''Federal Major Modification,'' all terms used in the definition are as defined in 40 CFR 51.165, as it exists on the date of adoption.

Additionally, Rule 2201 contains deficient definitions for the following terms: Major Source; Routine Maintenance, Repair and Replacement; PM_{10} Emissions; Secondary Emissions; and Volatile Organic Compounds. The specific deficiencies associated with these terms, and the necessary revisions necessary to correct the deficiencies, are described in the TSD for this proposed action.

2. Interpollutant Offset Requirements

Section 4.13.3.1 allows the District to approve interprecursor trading (IPT) of ozone precursors to satisfy emission offset requirements, provided certain conditions are satisfied. However, on January 29, 2021, the D.C. Circuit Court of Appeals in *Sierra Club* v. *EPA,* 984 F.3d 1055, issued a decision holding that the CAA does not allow IPT for ozone precursors and vacating the provisions in the EPA's NNSR regulations allowing IPT for ozone precursors. In light of the Court's decision, the provision in section 4.13.3.1 allowing for IPT for ozone precursors is no longer permissible. The District must revise section 4.13.3.1 to ensure it is consistent with the Courts decision and the provisions of 40 CFR 51.165(a)(11) as it pertains to ozone precursors.

3. Offset Exemptions

Sections 4.6.6 and 4.6.7 both allow exemptions from otherwise applicable offset requirements for the relocation of an entire stationary source or emission unit, respectively, if certain conditions are met. Because federal requirements do not allow any exemptions from offset requirements for relocation projects, we find these provisions deficient. The District may allow a source or emission unit to obtain emission reduction credits for the quantity of actual emissions previously emitted at the old location and use them as offsets at the new location. However, the full potential to emit (PTE) of the source or emission unit at the new location must be offset at the appropriate offset ratio. Alternatively, the District may limit the applicability of these exemptions to minor sources that are not subject to the NNSR offsetting requirements.

Section 4.6.8 provides an offset exemption for the installation or modification of required emission control equipment. Paragraph 4.6.8.4 establishes emissions increase limits for a project to qualify for this exemption but does not include a limit for $PM_{2.5}$ emissions and is therefore deficient. The District must update this provision to add a limit on increases in permitted emissions or potential to emit of no more than 10 tpy of $PM_{2.5}$. This will ensure that the exemption only applies to emission control projects that will not trigger a $PM_{2.5}$ major modification.

4. Public Notice Requirements for Minor Source Permits Emitting Ozone Precursors

Section 5.4.5 requires public notice for any project resulting in an increase in permitted emissions of any pollutant exceeding 20,000 pounds per year (10 tpy). As an extreme ozone nonattainment area, the major source threshold for ozone precursors is also 10 tpy, meaning that the rule currently does not require any public notice for minor sources of NO_X and VOC, whose emissions may contribute to ozone nonattainment in the San Joaquin Valley. Therefore, the public notice threshold does not adequately address the minor source and minor modification public notice requirements for VOC and NO_X. The District must demonstrate that its public notice threshold for minor sources of NO_X and VOC is sufficiently stringent to exclude only sources whose emissions are inconsequential to attainment.

5. District Equivalency With Federal Offset Requirements

Section 173 of the CAA and the EPA's implementing NSR regulations at 40 CFR 51.165 require emissions increases associated with new major sources and major modifications to be offset through corresponding decreases in emissions.

[6] 40 CFR 52.281(d).

To be creditable as offsets, these offsetting emissions reductions must be surplus, permanent, quantifiable, and federally enforceable,[7] and meet other federal requirements.

The EPA allows local permitting authorities flexibility in designing and implementing emissions offset programs, so long as these programs achieve an equal or greater amount of creditable emissions reductions as would be required under the offset program described in the federal NSR regulations. Rule 2201 differs from the federal offset requirements in several respects, including especially how it calculates ''surplus'' emission reductions required to offset emissions increases from new major sources and major modifications.

To account for these differences, Rule 2201 includes an offset equivalency tracking system in Section 7, which requires the District to submit an annual report comparing the offsets actually required by the District to those that would have been required under the federal requirements in terms of both the quantity of offsets required (''Test 1'') and the creditable ''time-of-use'' surplus value of the offsets (''Test 2'').[8]

If there is a shortfall under either Test 1 or Test 2, the District may supplement the demonstration by retiring additional creditable emission reductions that have not been used as offsets.[9] If the District cannot produce sufficient additional creditable emission reductions to make up a shortfall under either test, the failure triggers specific remedies under section 7.4. For a shortfall under Test 1, all new major source and major modification authority to construct (ATC) permits issued after the report deadline must apply the federal offset calculation requirements from 40 CFR 51.165 and part D of title I of the CAA, including the requirements to provide the federally required quantity of offsets and to ensure that these offsets are time-of-use surplus adjusted.[10] For a shortfall under Test 2, all new major source and major modification ATC permits issued after the report deadline must ensure that emissions reductions used to satisfy offset requirements are creditable and time-of-use surplus adjusted.[11]

The EPA first approved these provisions in 2004.[12] In the years since, the District has submitted annual equivalency demonstrations as described under the rule, showing equivalency under Test 1 and Test 2.[13] For many pollutants and years, the District has demonstrated equivalency on an annual basis, by collecting more offsets annually than required under the federal program.[14] However, tightened federal requirements resulting from the San Joaquin Valley's 2010 reclassification to Extreme ozone nonattainment has resulted in the District collecting, in some years, fewer annual offsets for VOC and NO_X than federally required. As a result, recent VOC and NO_X equivalency demonstrations have relied on ''carryover'' offsets collected in previous reporting years, as well as additional creditable emission reductions from facility closures that have not been claimed for offset credit by the facility operators (often termed ''orphan shutdowns''), and agricultural engine electrification projects.

The District's 2019–2020 Annual Offset Equivalency Report (''2019—2020 Report'') was the first to demonstrate a shortfall for any pollutant.[15] The 2019–2020 Report showed a failure of Test 1 and Test 2 for VOC, and a Test 2 failure for NO_X, and attributed these failures to the District's provisional removal of the additional creditable emission reductions associated with orphan shutdowns and engine electrification projects.[16] In response to the Report's VOC and NO_X failures, the District began implementing the federal offset requirements for VOC, and the federal requirements for offset surplus value (but not offset quantity) for NO_X, as described in the section 7 remedy provisions.[17]

The District's 2020–2021 Annual Offset Equivalency Report (''2020–2021 Report'') showed offset equivalency for PM_{10}, $PM_{2.5}$, CO, and SO_X.[18] The 2020–2021 Report did not include a Test 1 or Test 2 demonstration for VOC, or a Test 2 demonstration for NO_X, since the 2019–2020 Report found that the District's program was no longer showing equivalency under these tests. The 2020–2021 Report's Test 1 demonstration for NO_X showed that the District required fewer offsets in the reporting year than would have been required under federal offset requirements, but that the District's offset program maintained a sufficient balance of carryover offsets from previous reporting years to make up the difference. Critically, however, while NO_X offsets collected in the most recent reporting year were surplus adjusted to time-of-use pursuant to federal requirements (per the District's response to the prior year's Test 2 failure), the carryover offsets were credited at their full time-of-issuance value (*i.e.,* these offsets were not federally surplus-adjusted). Since the District's previous report had shown a Test 2 shortfall for NO_X offsets, these carryover offsets no longer retained any surplus balance that could be counted toward equivalency. The District subsequently issued a revised report withdrawing the NO_X portion of the 2020–2021 Report, based on the District's concern that the remedy of requiring a federal time-of use surplus adjustment was not adequate to ensure full federal equivalency.[19]

Since the shortfalls from the 2019–2020 and 2020–2021 Reports, several shortcomings in the District's equivalency system have become apparent. As an initial matter, the equivalency failures for VOC and NO_X mean that the District must update the rule to apply federal applicability and

[7] 40 CFR 51.165(a)(3)(ii)(C)(*1*)(*i*).

[8] ''Time-of-use'' surplus signifies that the offsetting emissions reductions are surplus of applicable requirements as of the issuance date of the ATC permit for the project whose emission increases the reductions are used to offset. The federal offset program requires all offsets to be time-of-use surplus. CAA 173(c)(2). In contrast, the quantity of offsets surrendered for construction permits issued by the District, as measured in Test 1, are surplus-adjusted only at the time the emission reduction credit is initially issued (''time-of-issuance'' surplus). Rule 2201 at section 3.2.2. Since emissions reductions may be credited years before they are used to offset a project, more stringent control requirements implemented in the interim period may significantly reduce the time-of-use surplus value relative to the time-of-issuance surplus value. Therefore, the District's allowance of ERCs valued at time-of-issuance is generally less stringent than federal requirements because it may assign higher value to a credit than is federally creditable.

[9] *Id.* at sections 7.2.1.2 and 7.2.2.2.

[10] *Id.* at section 7.4.1.2.

[11] *Id.* at section 7.4.2.1.

[12] 69 FR 27837 (May 17, 2004). The TSD for this proposed action includes more detail on the history of the Section 7 provisions and EPA's approval of the equivalency system.

[13] These reports are generally available at *www.valleyair.org/busind/pto/annual_offset_report/annual_offset_report.htm.*

[14] This has been most common for PM_{10}, CO, and SO_X, when the District has applied lower offsetting thresholds than applicable under the federal major source definitions at 40 CFR 51.165(a)(1)(iv)(A).

[15] SJVAPCD, ''2019–2020 Annual Offset Equivalency Report,'' November 20, 2020.

[16] Id. at 4–5. The District withdrew these credits in response to a CARB report that identified concerns about the assumptions and calculations that the District applied in crediting these reductions, among other issues associated with the District's implementation of its offset program. See CARB, ''Review of the San Joaquin Valley Air Pollution Control District Emission Reduction Credit System,'' June 2020.

[17] Rule 2201, section 7.4.1.2 and 7.4.2.1.

[18] SJVAPCD, ''2020–2021 Annual Offset Equivalency Report,'' November 19, 2021.

[19] SJVAPCD, ''2020–2021 Revised Annual Offset Equivalency Report,'' March 1, 2022 (''2020–2021 Revised Report''). See also letter dated March 21, 2022, from Elizabeth J. Adams, Director, EPA Region IX Air and Radiation Division, to Samir Sheikh, Executive Director, SJVAPCD (conveying EPA concerns about 2020–2021 Report NO_X demonstration, and supporting District decision to withdraw through 2020–2021 Revised Report).

offset requirements for these pollutants.[20] More generally, the 2020–2021 Report showed a significant disconnect between the section 7 tests and remedies for all pollutants. Specifically, once the District has failed Test 2, it has effectively demonstrated that its program is less stringent than the federal requirements because it has not provided an equivalent amount of time-of-use surplus emissions reductions as would have been required under the federal program.[21] However, the remedy for a Test 2 failure provides only that the District must require the offsets collected for future permits to be time-of-use surplus adjusted, and does not contain any explicit requirement for the District to collect the federal quantity of time-of-use surplus offsets for those permits. Therefore, the Test 2 remedy does not ensure full offset equivalency following a Test 2 failure.

Additionally, we identified a deficiency in Rule 2201 in that it does not contain any requirement to prevent the equivalency system from continuing to operate at a deficit once available carryover offsets and additional creditable emission reductions are exhausted. Because the rule only requires the District to demonstrate equivalency on an annual (rather than ongoing) basis, the District may continue to issue permits that require less than the federal quantity of surplus offsets even after the equivalency system has run out of excess offsets and emission reductions that can be used to restore the difference. This could allow the District to incur an increasing deficit for up to 15 months before any remedy is in place, since the rule's remedies become effective only after the submission deadline for the annual offset equivalency report.[22]

As described above, our 2004 approval of Rule 2201 found that an annual aggregate demonstration was generally appropriate and would not cause significant delay in implementing a remedy. However, this finding relies on demonstrations involving an annual shortfall that could be made up using carryover offsets, rather than a shortfall that exceeds the balance of available carryover offsets and additional creditable emission reductions within the equivalency system, as happened in the 2019–2020 Report.[23] On reconsideration, we find that an annual aggregate system may be inappropriate because it does not ensure that sufficient creditable emission reductions are available to offset emissions from new construction prior to an ATC permit being issued.[24] Moreover, we find that the specific provisions of Rule 2201 are inadequate because they do not contain any safeguards to prevent the District from continuing to operate its equivalency system with a negative balance during a reporting period.

Finally, because neither remedy provides a mechanism to require the District to quantify or restore a negative balance in the equivalency system, both remedies fail to ensure full federal offset equivalency in the event of a shortfall. Thus, even where the District adopts all offset requirements of the federal program in response to an equivalency failure, it will retain an historic deficit relative to the federal program, which is not made whole under the rule. Therefore, the EPA finds that the District must revise the rule to address these deficiencies.

The TSD for this proposed action includes suggestions for how the District can correct these deficiencies. We encourage the District to consult with Region 9 during the rule development process to ensure that all deficiencies are properly addressed.

6. Temporary Replacement Emission Units

The submitted version of Rule 2201 includes revisions to section 8.1.3 to provide an ''application shield'' for Temporary Replacement Emission Units (TREUs). An application shield is an administrative mechanism that allows a source to operate prior to submitting an application and obtaining an ATC, if certain conditions are met. While this provision is generally approvable, we have identified two deficiencies. First, the provision specifies that TREUs must be addressed by a best available retrofit control technology (BARCT) rule, but ''BARCT'' is not defined in Rule 2201 or the approved SIP. Second, the provision specifies that a TREU must be equipped with a control device that is ''capable'' of at least 85% emission control but does not specify any required minimum level of control that must actually be achieved. The definition of Routine Replacement Emissions Unit in section 3.35.5 of the existing rule also contains these same two deficiencies. These provisions must be revised to incorporate a definition of ''BARCT'' and to specify a minimum level of emission control to be achieved.

7. Other Deficiencies

The TSD for this proposed action describes several other federal NNSR requirements not addressed in Rule 2201. These include the following: stack height requirements at 40 CFR 51.164; enforceable procedures as provided at 40 CFR 51.165(a)(5)(i) and (ii); and permit issuance restrictions based on inadequate SIP implementation at CAA section 173(a)(4). This section of the TSD also notes that the rule contains a cross-reference to a State statutory provision that should be clarified with an applicable date. See our discussion in Section 6.3.6 of the TSD for more information on these deficiencies.

D. EPA Recommendations to Further Improve the Rule

The TSD includes recommendations for the next time the SJVAPCD modifies Rule 2201.

E. Proposed Action and Public Comment

As authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is proposing a limited approval and limited disapproval of Rule 2201. We will accept comments from the public on this proposal until August 29, 2022. If we finalize this action as proposed, this action will incorporate Rule 2201 into the SIP, including those provisions identified as deficient. This approval is limited because EPA is simultaneously proposing a limited disapproval of the rule under section 110(k)(3). If finalized as proposed, our limited disapproval action would trigger an obligation on the EPA to promulgate a Federal Implementation Plan unless the State corrects the deficiencies, and the EPA approves the related plan revisions, within two years of the final action. Additionally, because the deficiency relates to NNSR requirements under part D of title I of the Act, the offset sanction in CAA section 179(b)(2) would apply in the San Joaquin Valley 18 months after the effective date of a

[20] See Rule 2201, section 7.4.1.2.

[21] See CAA 173(a)(1)(A) (requiring state NSR programs to obtain ''sufficient offsetting emissions reductions'' as determined by federal NSR regulations).

[22] See Rule 2201 at section 7.4.1.2 and 7.4.2.1. Fifteen months represents the outermost time for a shortfall to be addressed, running from the start of a reporting year (August 20) to the reporting deadline (November 20 of the following year). We note that the District initiated federal time-of-use surplus adjustments for VOC and NO_X once it could no longer demonstrate Test 2 equivalency for these pollutants, consistent with the Test 2 remedy but prior to the reporting deadline. We recognize this as a voluntary correction consistent with the District's provisional withdrawal of additional creditable reductions of these pollutants, rather than a requirement of the existing rule text.

[23] See 69 FR 27837, 27841.

[24] See CAA sections 173(a) and 173(c)(1) (specifying that emission reductions used to offset a new or modified major source must be federally enforceable before a permit for the source is issued, and must be in effect and enforceable by the time the source commences operation). See also CAA section 173(a)(1)(A) (requiring sufficient emissions reductions to have been ''obtained'' by the time the source commences operation).

final limited disapproval, and the highway funding sanctions in CAA section 179(b)(1) would apply in the area six months after the offset sanction is imposed. Neither sanction will be imposed under the CAA if the State submits and we approve, prior to the implementation of the sanctions, a SIP revision that corrects the deficiencies we identify in our final action. The EPA intends to work with the SJVAPCD to correct the deficiencies in a timely manner.

Note that Rule 2201 has been adopted by the SJVAPCD, and the EPA's final limited disapproval would not prevent the local agency from enforcing it. The limited disapproval would also not prevent any portion of the rule from being incorporated by reference into the federally enforceable SIP.[25]

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the rule discussed in Section I. and listed in Table 1 of this preamble. The EPA has made, and will continue to make, this document available electronically through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

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

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

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

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

Dated: July 25, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2022–16245 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

[25] Memorandum dated July 9, 1992, from John Calcagni, Director, Air Quality Management Division, Office of Air Quality Planning and Standards, U.S. EPA, to EPA Regional Air Directors, Regions I–X, Subject: ''Processing of State Implementation Plan (SIP) Submittals.''

Notices

Federal Register
Vol. 87, No. 145
Friday, July 29, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 29, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Family Day Care Home (FDCH) Participation Study.

OMB Control Number: 0584–NEW.

Summary of Collection: The Child and Adult Care Food Program (CACFP), administered by the Food and Nutrition Service (FNS), plays a critical role in supporting the health and wellness of children by reimbursing providers for nutritious meals served to eligible children in their care. The FDCH Participation Study aims to understand FDCH provider experiences with the CACFP by asking a nationally representative sample of both current and former CACFP-participating FDCH providers about their experiences with the program.

Need and Use of the Information: The primary data collection activity will include the FDCH Provider Experience Survey, designed to gather information from FDCH providers to address the three main objectives for the study:

1. Identify and describe the reasons why FDCH providers discontinue their participation in CACFP;

2. Determine and describe CACFP program statutory and regulatory requirements, operational and financial considerations, and Federal, State, and local specifics frequently cited as burdensome by stakeholders. Classify challenges as Federal, State, and local and describe in detail; and

3. Gather and summarize recommendations from FDCH providers on how to reduce barriers or challenges to CACFP participation.

Description of Respondents: State, Local, or Tribal government, Businesses or other For- Profit and Not-for-Profit.

Number of Respondents: 5,921.

Frequency of Responses: Reporting: Once.

Total Burden Hours: 4,623.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–16241 Filed 7–28–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 29, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Standards for Privately Owned Quarantine Facilities for Ruminants.

OMB Control Number: 0579–0232.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law

gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material to prevent the spread of any livestock or poultry pest or disease. The Animal and Plant Health Inspection Service (APHIS) provides standards for the approval, operation, and oversight of privately owned quarantine facilities for imported ruminants prior to their release into the United States. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of Public Law 107–171, May 13, 2002, the Farm Security and Rural Investment Act of 2002 [7 U.S.C. 8301 *et seq.*].

Need and Use of the Information: APHIS uses the following information activities with its efforts to maintain a system whereby private individuals can operate (with APHIS oversight) their own facilities for the quarantine of imported ruminants: (1) Application Letter; (2) Cooperative Service Agreement; (3) Daily Log and Recordkeeping; (4) Request for Variance; and (5) Operating Procedures and Recordkeeping. Without the information, APHIS would be forced to discontinue its program of allowing the operation of privately owned quarantine facilities for ruminants, a development that would hamper U.S. animal import activities.

Description of Respondents: Business or other for-profit and State.

Number of Respondents: 5.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 64.

Animal and Plant Health Inspection Service

Title: Irradiation Treatment; Location of Facilities in the United States.

OMB Control Number: 0579–0383.

Summary of Collection: The United States Department of Agriculture (USDA) is responsible for preventing plant diseases or insect pests from entering into the United States, preventing the spread of pests and noxious weeds not widely distributed into the United States, and eradicating those imported pests when eradication is feasible. The Plant Protection Act (7 U.S.C. 7701 *et seq.*) authorizes USDA to carry out this mission. Under the Plant Protection Act, the Animal and Plant Health Inspection Service (APHIS) is authorized, among other things, to regulate the importation of plants, plant products, and other articles to prevent the introduction of plant pests in the United States.

Need and Use of the Information: APHIS will use the following information collection activities to provide criteria for the approval/certification of irradiation treatment facilities in an effort to prevent the introduction or spread of plant pests and plant diseases in the United States: Request for Initial Certification and Inspection of Facility; Certification and Recertification of Facility; Denial and Withdrawal of Certification; Compliance Agreement; Irradiation Facilities Treating Imported Articles; Irradiation Treatment Framework Equivalency Work plan; Irradiation Facilities Notification; Recordkeeping; Facility to Maintain and Provide Updated Map Identifying Places Horticultural/Crops are Grown; Facility Contingency Plan; Letter of Concurrence or Non-Agreement; Treatment Arrangements; Pest Management Plan; and Facility Map—Detailed Layout of Facility. If the information is not collected, APHIS would have no practical way of determining that any given commodity had actually been irradiated.

Description of Respondents: Business or other for-profits; Federal Government; State, Local or Tribal Government.

Number of Respondents: 24.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 988.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–16342 Filed 7–28–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program Waivers Under the Food and Nutrition Act

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this planned information collection. This is a revision of a currently approved collection. Section 6(o) of the Food and Nutrition Act establishes a time limit of the receipt of benefits under the Supplemental Nutrition Assistance Program (SNAP) for certain able-bodied adults without dependents (ABAWDs) who are not working. The provision authorizes the Secretary of Agriculture, upon a State agency's request, to waive the time limit for any group of individuals if the Secretary determines ''that the area in which the individuals reside has an unemployment rate of over 10 percent, or does not have a sufficient number of jobs to provide employment for the individuals.'' As required by the statute, to receive a waiver, the State agency must submit sufficient supporting information so that the United States Department of Agriculture (USDA) can make the required determination as to the area's unemployment rate or insufficiency of available jobs. This collection of information is, therefore, necessary to obtain waivers of the SNAP time limit. In October 2020, the U.S. District Court in District of Columbia vacated the final rule titled, ''Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults Without Dependents''. USDA is revising the hours associated with this collection to reflect the return to regulations prior to the final rule.

DATES: Written comments must be received on or before September 27, 2022.

ADDRESSES: Comments may be sent to: Certification Policy Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via fax to the attention of the Certification Policy Branch or via email to *SNAPCPBRules@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to the Alison Conrad at 703–305–2022.

SUPPLEMENTARY INFORMATION:

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality,

utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program Waivers of Section 6(o) of the Food and Nutrition Act.

Form Number: N/A.

OMB Control Number: 0584–0479.

Expiration Date: 1/31/2023.

Type of Request: Revision of a currently approved collection.

Abstract: Section 6(o) of the Food and Nutrition Act of 2008 establishes a time limit for the receipt of Supplemental Nutrition Assistance Program (SNAP) benefits for certain able-bodied adults without dependents (ABAWDs) who are not working at least 20 hours per week. This time limit applies only to adults between 18 and 50 years of age that do not have children or adult dependents in their SNAP household. ABAWD recipient eligibility is limited to three months within a 36-month period, unless the individual is working, or participating in a designated employment and training activity, for 20 hours per week.

The provision authorizes that upon the request of a State agency, the Secretary of Agriculture may waive this provision for any group of individuals if the Secretary determines ''that the area in which the individuals reside has an unemployment rate of over 10 percent or does not have a sufficient number of jobs to provide employment for the individuals.'' As required in the statute, to receive a waiver, the State agency must submit sufficient supporting information so that the Secretary can make the required determination as to the area's unemployment rate or insufficiency of available jobs. This collection of information is necessary to obtain waivers of the SNAP ABAWD time limit.

State agencies submit formal requests to waive the ABAWD time limit to the Food and Nutrition Service (FNS) for approval through the electronic Waiver Information Management System (WIMS). In their requests, State agencies (1) designate the areas where they wish to waive the time limit, (2) explain the criteria for which those areas qualify for a waiver, and (3) provide required data to justify their request. A typical State waiver request includes several geographic areas, and each geographic area may include multiple cities or counties. FNS reviews the requests and supporting information to ensure that all necessary requirements to waive the time limit are met.

On December 5, 2019, FNS published the final rule, ''Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults Without Dependents'' (84 FR 66782). This rule significantly increased the reporting burden associated with this information collection, primarily because of the start-up costs associated with the rule, and adjusted the estimates of the type of data States would use to support their ABAWD waiver requests. When the U.S. District Court for the District of Columbia vacated this rule on October 18, 2020, the previous regulations were reinstated. As a result, the reporting burden estimates for this information collection have decreased with this revision to reflect the return to regulations prior to the final rule.

Based on FNS's experience in Fiscal Years (FY) 2018 through 2021, FNS projects that 35 out of 53 State agencies will submit requests for a waiver of the time limit for ABAWD recipients based on a high unemployment rate or an insufficient number of jobs. Based on requests submitted and approved in FY 2019, FNS projects that of the 35 requests each year, 33 will use labor market data and two will use the Department of Labor's (DOL) Labor Surplus Area (LSA) designations or an extended unemployment benefits (EB) trigger notice to request a waiver. FNS is using only FY 2019 as the baseline for this part of the estimate because of the unique circumstances affecting the data States submitted to support their ABAWD waiver requests in FYs 2020 through 2022, as explained below.

In late FY 2019 through late FY 2020, States submitted ABAWD waiver requests using the criteria outlined in the final rule titled, ''Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults Without Dependents'' (84 FR 66782). As mentioned above, the U.S. District Court for the District of Columbia vacated this rule on October 18, 2020, and States no longer request ABAWD waivers using these methods. In FY 2020 through FY 2022, the ABAWD time limit was partially suspended by the Families First Coronavirus Relief Act (Pub. L. 116–127), and States primarily supported their waivers using EB trigger notices because of the economic impact of the COVID–19 pandemic. This simplified the waiver request process for States and reduced the amount of time it takes to compile and share the data to support the waiver request. FNS does not expect a significant number of States to qualify for EB trigger notices beyond FY 2022, having already seen a drop-off in calendar year 2022 qualifications. FNS anticipates States currently using this criterion to switch to requests using labor market data in the future, which takes more time to compile.

In line with the estimates included in the 2018 renewal of this information collection, FNS provides two estimates for the burden of preparing and submitting waiver requests based on the waiver criteria used. For the first waiver criteria in the burden chart below, FNS estimates a response time for this activity is approximately 35 hours to prepare and submit via WIMS for each waiver request based on labor market data, which require detailed analysis of labor markets within the State using Bureau of Labor Statistics or a cooperating agency's data.

For the second criteria in the burden chart below, FNS estimates a burden of four hours per respondent to prepare and submit via WIMS waivers based on an LSA designation or an EB trigger notice, as the data required to support these waivers is readily available from the DOL website and requires minimal preparation by State agencies.. FNS projects a total annual burden of 1,163 hours and 35 responses (33 responses based on labor market data and two responses based on an LSA designation or EB trigger notice). This revision results in a decrease of 170,093 hours and 2,174,037 responses as a result of program changes.

Reporting

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: 35.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 35.

Estimated Time per Response: 33.23.

Estimated Total Annual Burden on Respondents: 1,163 Hours.

There is no recordkeeping or third party reporting requirement directly associated with this information collection.

Respondent category	Type of respondents	Burden activity	CFR citation	Estimated number of respondents	Responses per respondent	Total annual responses	Estimated hours per response	Estimated total burden hours
State Agency	State Program Staff.	Preparation and submission of Labor Market Data to support ABAWD waiver request.	7 CFR 273.24(f).	33	1	33	35	1,155
State Agency	State Program Staff.	Preparation and submission of Labor Surplus Area designation or EB Trigger Notice criteria to support ABAWD waiver request.	7 CFR 273.24(f).	2	1	2	4	8
Total	.....	.....	.....	35	1	35	33.23	1,163

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–15796 Filed 7–28–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Final Record of Decision for the Santa Fe Forest

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of approval of the Revised Land Management Plan for the Santa Fe National Forest.

SUMMARY: James Duran, the Acting Forest Supervisor for the Santa Fe National Forest, Southwestern Region, signed the final record of decision (ROD) for the Santa Fe National Forest Land Management Plan (LMP). The final ROD documents the rationale for approving the LMP and is consistent with the Reviewing Officer's responses to objections and instructions.

DATES: The revised LMP for the Santa Fe National Forest will become effective [30 days after the publication of this notice of approval in the **Federal Register** (36 CFR 219.17(a)(1)).

ADDRESSES: To view the final ROD, final environmental impact statement (FEIS), the revised LMP, and other related documents, please visit the Santa Fe National Forest website at: *www.fs.usda.gov/goto/santafeforestplan.*

A legal notice of approval is also being published in the newspaper of record, *The Albuquerque Journal.* A copy of this legal notice will be posted on the Santa Fe National Forest's website described above.

FOR FURTHER INFORMATION CONTACT: Sarah Browne, Acting Forest Planner, Santa Fe National Forest, by telephone 505–438–5442, or via email at *santafeforestplan@usda.gov.*

Individuals who use telecommunication devices for the deaf or hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays. Written requests for information may be sent to Santa Fe National Forest, Attn: Santa Fe National Forest Plan Revision, 11 Forest Lane, Santa Fe, NM 87508.

SUPPLEMENTARY INFORMATION: The Santa Fe National Forest covers five ranger districts and more than 1.6 million acres across six counties in northern New Mexico. The LMP was developed pursuant to the 2012 Forest Service Planning Rule (36 CFR 219) and will replace the 1987 LMP. The LMP describes desired conditions, objectives, standards, guidelines, and land suitability for project and activity decision-making and will guide all resource management activities on the Forest. The Santa Fe National Forest plays an important role supporting and partnering with communities in northern New Mexico and throughout the southwestern United States by providing economic benefits including fuelwood gathering, livestock grazing, and abundant recreational opportunities. The development of the LMP was shaped by the best available scientific information, current laws, and public input.

The Santa Fe National Forest initiated plan revision in 2014 and engaged the public frequently throughout the process. This engagement effort has included conventional public meetings, collaborative work sessions and technical meetings, information sharing via social media, and working with cooperating agencies. The Forest invited State, local, Tribal governments, and other Federal agencies from around the region to participate in the process to revise the LMP. The Forest engaged in government-to-government consultation with 24 tribes during LMP revision, ensuring tribal-related plan direction accurately reflects the Santa Fe National Forest's trust responsibilities and government-to-government relationship with tribes. An interagency working group met regularly throughout the plan revision effort. During the 90-day comment period in 2019 for the draft LMP and draft EIS, the Santa Fe National Forest received over 13,600 comments which helped refine the preferred alternative and augment plan content based on response to comments.

A draft ROD, LMP, and FEIS were released in September 2021, initiating a 60-day objection filing period that closed November 2, 2021. The Santa Fe received 15 eligible objections. Through a comprehensive review of each objection, a variety of issues were identified. Following the objection review, the Reviewing Officer held objection resolution meetings with objectors and interested persons. Based on these meetings, the Reviewing Officer issued a written response on May 24, 2022. The instructions from the Reviewing Officer were addressed in the ROD, LMP, and FEIS.

Responsible Official: The Responsible Official for approving the LMP is James Duran, Acting Forest Supervisor, Santa Fe National Forest. The Responsible Official approving the list of species of conservation concern is Michiko Martin, Regional Forester, Southwestern Region.

Dated: July 26 2022.

Deborah Hollen,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–16318 Filed 7–28–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Community Wildfire Defense Grant Program

AGENCY: Forest Service, Department of Agriculture (USDA).

ACTION: Notice of funding opportunity; emergency collection; request for comment.

SUMMARY: U.S. Department of Agriculture's Forest Service announces the availability of up to $1 billion in grant funding, appropriated under the Infrastructure Investment and Jobs Act, for the establishment of the Community Wildfire Defense Grant (CDWG) Program. As authorized under the Infrastructure Investment and Jobs Act,

funds will be made available and distributed to eligible applicants within the footprints of the Western States, Northeast-Midwest States, Southern States, and Indian Tribes/Alaska Native Corporations. There are two primary project types for which the CDWG provides funding: the development and revising of Community Wildfire Protection Plans (CWPP) and the implementation of projects described in a CWPP that is less than ten years old. The Act prioritizes at-risk communities that are in an area identified as having high or very high wildfire hazard potential, are low-income, and/or have been impacted by a severe disaster.

DATES: Applications for the FY2022 CDWG must be submitted per the included instructions on *grants.gov* by 11:59 p.m., Eastern Time zone, October 7, 2022.

- For Indian Tribes/Alaska Native Corporations, search for the following grant Opportunity Number in *grants.gov* and follow the included instructions: USDA–FS–2022–CWDG–TRIBES. Please note that Indian Tribes/Alaska Native Corporations can apply through either this specific grant opportunity or the applicable regional notice (Western States, Northeast-Midwest States, or Southern States) listed below.
- For the Western States of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming, and for the Territory of American Samoa, the Republic of Palau, the Federated States of Micronesia, the Territory of Guam, the Commonwealth of Northern Mariana Islands, and the Republic of the Marshall Islands, search for the following grant Opportunity Number in *grants.gov* and follow the included instructions: USDA–FS–2022–CWDG–CWSF.
- For the Northeast-Midwest States of Connecticut, Delaware, Illinois, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont, West Virginia and Wisconsin, and for the District of Columbia, search for the following grant Opportunity Number in *grants.gov* and follow the included instructions: USDA–FS–2022–CWDG–NEMW.
- For the Southern States of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia, and for Puerto Rico and the U.S. Virgin Islands, search for the following grant Opportunity Number in *grants.gov* and follow the included instructions: USDA–FS–2022–CWDG–SGSF.

Applications received after 11:59 p.m., Eastern Time zone, October 7, 2022, will not be considered.

Comments related to the collection of information must be submitted by September 27, 2022 to be assured of consideration. Comments received after that date will be considered to the extent practicable. Please follow the directions provided in Paperwork Reduction Act section of this notice.

ADDRESSES: This funding opportunity will be made available on *grants.gov.* Applicants are strongly encouraged to reach out to the relevant State Forester and Forest Service Cooperative Fire Specialist during application development to ensure the project aligns with program purpose and eligibility and receive input to strengthen your application.

Comments concerning this notice should be addressed to: USDA, Forest Service, Attention Sheila Walker, USDA Forest Service, Washington Office, Fire and Aviation Management (FAM), 1400 Independence Avenue Southwest, Mailstop 1107, Washington, DC 20250. Comments may also be submitted via email to: *Sheila.Walker2@usda.gov.* The public may inspect comments received at USDA Forest Service, Washington Office during normal business hours. Visitors are encouraged to call ahead to 202–205–0995 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Sheila Walker, Fire and Aviation Management by phone at 503–313–2784 or email at *Sheila.Walker2@usda.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA), 5 U.S.C. 801 *et seq.,* the Office of Information and Regulatory Affairs in the Office of Management and Budget designated this action as a major rule as defined by 5 U.S.C. 804(2), (Pub. L. 104–121), because it is likely to result in an annual effect on the economy of $100,000,000 or more. Accordingly, there is a 60-day delay in the effective date of this action. Application rating, ranking, and selection will not begin until after October 7, 2022. Therefore, the 60-day delay required by the CRA is not expected to have a material impact upon the administration and/or implementation of the Community Wildfire Defense Grant Program.

Overview

Federal Agency: Forest Service, USDA.

Funding Opportunity Title: Community Wildfire Defense Grant (CDWG) Program.

Funding Opportunity Numbers: USDA–FS–2022–CWDG–TRIBES, USDA–FS–2022–CWDG–CWSF, USDA–FS–2022–CWDG–NEMW, and USDA–FS–2022–CWDG–SGSF.

Announcement Type: Notice of Funds Opportunity.

Assistance Listings (AL) Number: 10.720.

Due Date for Applications: Applications for the FY2022 CDWG must be submitted per the included instructions on *grants.gov* by 11:59 p.m., Eastern Time zone, October 7, 2022. Applications received after 11:59 p.m., Eastern Time zone, October 7, 2022, will not be considered.

Informational Webinars: Four (4) informational webinars will be provided to any interested applicants, one designed for each separate Notice of Funding Opportunity. These webinars will occur during the first two weeks of August 2022 and will be recorded for future viewing. Specific information regarding the webinars, including dates, times, and registration information, will be made available on the following web page: *www.fs.usda.gov/managing-land/fire/grants.*

Background

The purpose of the Community Wildfire Defense Grant (CWDG) is to assist at-risk local communities and Indian Tribes with planning for and mitigating against the risk created by wildfire. This program is authorized in H.R. 3684, ''An Act to authorize funds for Federal-aid highways, highway safety programs, and transit programs, and for other purposes,'' commonly referred to as the Infrastructure Investment and Jobs Act. Specifically, the CWDG is provided for in Title VIII, Section 40803. There are two primary project types for which the grant provides funding: the development and revising of Community Wildfire Protection Plans (CWPP) and the implementation of projects described in a CWPP that is less than ten years old. The Act prioritizes at-risk communities that are in an area identified as having high or very high wildfire hazard potential, are low-income, and/or have been impacted by a severe disaster.

More details on these three priorities can be found on *grants.gov*.

The CWDG helps communities in the wildland urban interface (WUI) implement the three goals of the National Cohesive Wildland Fire Management Strategy (Cohesive Strategy):

- *Restore and Maintain Landscapes:* Landscapes across all jurisdictions are resilient to fire-related disturbances, in accordance with management objectives.
- *Create Fire Adapted Communities:* Human populations and infrastructure can withstand a wildfire without loss of life and property.
- *Improve Wildfire Response:* All jurisdictions participate in making and implementing safe, effective, efficient risk-based wildfire management decisions.

Key Points

- *Who Can Apply:* Entities eligible to apply for funding under the CWDG include:

a. Units of local governments representing communities located in an area with a risk of wildfires,

b. Indian Tribes (please apply through either the Indian Tribes/Alaska Native Corporations specific notice or the applicable regional notice),

c. Non-profit organizations including homeowner associations that assist such communities,

d. State forestry agencies (including U.S. territories and interests), and

e. Alaska Native Corporations (please apply through either the Indian Tribes/ Alaska Native Corporations specific notice or the applicable regional notice).

For-profit entities are not eligible to apply for this funding opportunity.

- *Eligible Lands:* Eligible applicants may apply for grant funding for a project proposal to be conducted on lands with the following ownership types, as long as the project proposal directly reduces wildfire risk to a community:

a. Private lands,

b. Local government,

c. Homeowner associations,

d. State government, and

e. Tribal/Alaska native corporation (includes Trust lands).

Lands administered by the federal government are not eligible for this funding opportunity with the exception of lands held in trust for Native American Tribes and individuals (Trust lands).

- *State Forest Action Plans and the Cohesive Wildland Fire Management Strategy:* Projects should further the priorities, *e.g.,* goal, strategy, and/or priority landscape, in the most recent State Forest Action Plans as well as the relevant regional cohesive wildland fire management strategy document.
- *Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government:* We prioritize applications that show a clear benefit to underserved people and the communities where they reside or the forest areas that they value. Where this is the case, this should be described in the ''Project Narrative Form.'' Underserved communities are also eligible to request a waiver of match requirements.
- *Minimum and Maximum Funding Levels:*

a. There is no *minimum* Federal funding limit for projects under CWDG.

b. The *maximum* amount of Federal funding awarded to any one community or Tribe via this competitive process is:

- $250,000 for the creation or updating of a Community Wildfire Protection Plan, and
- $10 million for a project described within a Community Wildfire Protection Plan less than 10 years old.

c. For planning purposes, the Federal funding allocated through the CWDG competitive process is expected to be approximately $160 million annually for the next five years.

- *Required Matching Funds:* The CWDG program has differing levels of match dependent upon the proposal for which is being applied. For proposals to develop or update a CWPP, the required match is 10%. For proposals to implement projects described within a CWPP, the required match is 25%. Matching funds must be derived entirely from non-Federal sources (unless expressly authorized in law by the other federal program). The match must be met by eligible and allowable costs and is subject to match provisions in grant regulations (Code of Federal Regulations Title 2 Part 200.306 and Subpart E for Cost Principles). Match must meet all the same requirements as the Federal share and be documented sufficiently to support financial tracking and accountability. *Communities meeting the definition of underserved may request a waiver of match;* no other waiver requests are allowable under this program.
- *Lead Agency or Organization:* All applications must identify the lead agency or organization that will have primary responsibility for coordinating project work and reporting. The lead agency may pass funds to other partners performing work as relevant.
- *Grant Timeframes:* Projects must be completed within five (5) years.
- *For Proposals including multiple communities:* For separate projects in separate communities, a separate narrative form and included budget will need to be filled out for each community for purposes of determining eligibility, prioritization, and ranking. For an application consisting of a single project that spans multiple communities, the project can be applied for and described within the same application and narrative form.
- *Scoring and Ranking of applications:* Applications will be scored by members of a regional review panel. Individual reviewer scores will be normalized. All regionally-scored applications will be compiled in a single nationally-ranked list, which will be used to distribute funding.
- *Reporting:* Funded CWDG projects will be required to provide financial reports to the grant's administrator on a quarterly basis, and project performance reports on an annual basis. The annual performance report shall include a spatial data component. This requires both Forest Service grant monitors and CWDG grant recipients to coordinate in entering project information.
- *Build America/Buy America:* The Build America, Buy America Act, enacted as part of the Infrastructure Investment and Jobs Act, established a domestic content procurement preference for all Federal financial assistance obligated for infrastructure projects after May 14, 2022. The Buy America preference requires that all iron, steel, manufactured products, and construction materials used in infrastructure projects are produced in the United States. If a recipient proposes a waiver of the Buy America preference, they must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted.
- *Environmental Compliance:* The requirements of the National Environmental Policy Act (NEPA) apply to proposed ''Federal'' actions. Whether an action under the CWDG program may be subject to NEPA analysis is dependent upon the level of federal (Forest Service) control and authority over the action. Deciding whether or not the Forest Service is responsible for performing NEPA analysis is determining whether the Forest Service exercises control over the implementation of the action to be funded, and to what degree implementation of the action is dependent upon Forest Service funding. For example, where the Forest Service provides funding, but does not exercise control or decision making over the specific projects and actions funded by the CWDG grant, it is unlikely to be

deemed a Federal action for purposes of requiring NEPA analysis. Similarly, where the Forest Service provides only a small percentage of the funding for a project, it is unlikely that environmental analysis will be required under NEPA due to limited control and responsibility.

• *Floodplain Management Criteria:* If applicable and appropriate, a project located in a Special Flood Hazard Area must implement and meet the conditions contained within the Federal Flood Risk Management Standard (FFRMS).

• *Labor Standards:* All laborers and mechanics employed by the applicant, subrecipients, contractors or subcontractors in the performance of construction, alteration, or repair work on an award or project in excess of $2,000 funded directly by or assisted in whole or in part by funds made available under this grant program shall be paid wages at rates not less than those prevailing on similar projects in the locality, as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of title 40, United States Code commonly referred to as the ''Davis-Bacon Act'' (DBA).

Applicants shall provide written assurance acknowledging the DBA requirements for the award or project and confirming that all laborers and mechanics performing construction, alteration, or repair work on projects in excess of $2,000 funded directly by or assisted in whole or in part by and through funding under the award are paid or will be paid wages at rates not less than those prevailing on projects of a character similar in the locality as determined by the Secretary of Labor in accordance with Subchapter IV of Chapter 31 of Title 40, United States Code (Davis-Bacon Act).

Recipients of funding will also be required to undergo DBA compliance training and to maintain competency in DBA compliance. The U.S. Department of Labor offers free Prevailing Wage Seminars several times a year that meet this requirement, at *https://www.dol.gov/agencies/whd/government-contracts/construction/seminars/events.*

For additional guidance on how to comply with DBA provisions and clauses, see *https://www.dol.gov/agencies/whd/government-contracts/construction* and *https://www.dol.gov/agencies/whd/government-contracts/protections-for-workers-in-construction.*

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), USDA requested that the Office of Management and Budget (OMB) conduct an emergency review by July 26, 2022, of a new information collection that contains the CDWG Information Collection and Recordkeeping requirements.

In addition to the emergency clearance, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under a full comment period, as the Agency intends to request regular approval from OMB for this information collection. Comments from the public on new, proposed, revised, and continuing collections of information help us assess the impact of our information collection requirements and minimize the public's reporting burden. Comments may be submitted regarding this information collection by the following method:

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and, in the ''Search'' box, type in the Docket No. USDA–2022–0017. Follow the online instructions at that site for submitting comments. This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Information on using *regulations.gov,* including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''FAQ'' link at the bottom. Comments on this information collection must be submitted by September 27, 2022 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. Data furnished by the applicants will be used to determine eligibility for program benefits. Furnishing the data is voluntary; however, failure to provide data could result in program benefits being withheld or denied.

Title: Community Wildfire Defense Grant Program.

OMB Number: 0596–NEW.

Type of Request: New Information Collection.

Abstract: The Community Wildfire Defense Grant Program forms will be used by applicants to apply for the Community Wildfire Defense Grant (CWDG) Program. The purpose of the CWDG Program is to assist at-risk local communities and Indian Tribes with planning and mitigating against the risk created by wildfire. This program is authorized in the Infrastructure Investment and Jobs Act (Pub. L. 117–58), commonly referred to as the Bipartisan Infrastructure Law (BIL). Specifically, the CWDG Program is provided for in Title VIII, Section 40803. There are two primary project types for which the grant provides funding: the development and revision of Community Wildfire Protection Plans (CWPP) and the implementation of projects described in a CWPP that is less than ten years old. The Act prioritizes at-risk communities that are in an area identified as having high or very high wildfire hazard potential, are low-income, and/or have been impacted by a severe disaster.

Burden Hours for Community Wildfire Defense Grant Program Project Narrative Form

Estimate of Annual Burden: 1.25 hours.

Type of Respondents: Public applicants.

Estimated Annual Number of Respondents: 500.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 625 hours.

The burden for the Narrative Form includes submission of documentation of at-risk community, wildfire hazard potential, low-income, and/or impacted by a severe disaster as well as any maps or photos to accompany the narrative.

Burden Hours for Community Wildfire Defense Grant Program Project Narrative Form

Estimate of Annual Burden: 1.25 hours.

Type of Respondents: Tribal applicants.

Estimated Annual Number of Respondents: 100.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 125 hours.

The burden for the Narrative Form includes submission of documentation of at-risk community, wildfire hazard potential, low-income, and/or impacted by a severe disaster as well as any maps or photos to accompany the narrative.

Burden Hours for Application for Federal Assistance 424

Estimate of Annual Burden: 1 hour.

Type of Respondents: Public applicants.

Estimated Annual Number of Respondents: 100.

Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 100 hours.

Burden Hours for Application for Federal Assistance 424:

Estimate of Annual Burden: 1 hour.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 100.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 100 hours.

Burden Hours for BUDGET INFORMATION—Non-Construction Programs 424a

Estimate of Annual Burden: 1 hour.
Type of Respondents: Public applicants.
Estimated Annual Number of Respondents: 100.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 100 hours.

Burden Hours for BUDGET INFORMATION—Non-Construction Programs 424a

Estimate of Annual Burden: 1 hour.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 100.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 100 hours.

Burden Hours for Community Wildfire Defense Grant Program Annual Performance Report

Estimate of Annual Burden: 2.00 hours.
Type of Respondents: Public applicants.
Estimated Annual Number of Respondents: 400.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 800 hours.

Burden Hours for Community Wildfire Defense Grant Program Annual Performance Report

Estimate of Annual Burden: 2.00 hours.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 80.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 160 hours.

Burden Hours for Community Wildfire Defense Grant Program System for Award Management Screenshot

Estimate of Annual Burden: 0.10 hours.
Type of Respondents: Public applicants.
Estimated Annual Number of Respondents: 400.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 40 hours.

Burden Hours for Community Wildfire Defense Grant Program System for Award Management Screenshot

Estimate of Annual Burden: 0.10 hours.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 80.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 8 hours.

Burden Hours for Community Wildfire Defense Grant Program Davis-Bacon Act Written Assurance

Estimate of Annual Burden: 0.10 hours.
Type of Respondents: Public applicants.
Estimated Annual Number of Respondents: 500.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 50 hours.

Burden Hours for Community Wildfire Defense Grant Program Davis-Bacon Act Written Assurance

Estimate of Annual Burden: 0.10 hours.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 100.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 10 hours.

Burden Hours for Community Wildfire Defense Grant Program Audit Requirements

Estimate of Annual Burden: 24.00 hours.
Type of Respondents: Public applicants.
Estimated Annual Number of Respondents: 25.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 600 hours.

Burden Hours for Community Wildfire Defense Grant Program Audit Requirements:

Estimate of Annual Burden: 24.00 hours.
Type of Respondents: Tribal applicants.
Estimated Annual Number of Respondents: 10.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 240 hours.

Comment Is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Civil Rights

Programs referenced in this Notice are subject to applicable Civil Rights Laws. These laws include the Equal Credit Opportunity Act, Title VI of the Civil Rights Act of 1964, Title VIII of the Civil Rights Act of 1968, and Section 504 of the Rehabilitation Act of 1973.

Intergovernmental Review

The CDWG Program is subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' Submit one copy of the application to the State government single point of contact, if one has been designated, at the same time as application submission to the Agency. If the project is located in more than one state, submit a copy to each applicable state government single point of contact. Go to *https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf* for state office contact information. Applications from Federally recognized Indian tribes are not subject to this requirement.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 requires federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications. The Forest Service consulted and provided an overview of the CWDG program to Tribal entities in coordination with the FS Office of Tribal Relations. In addition, a tribal liaison was a member of the stakeholder group developing the program. An informational webinar specific to Tribes will occur during the first two weeks of August 2022 and will be recorded for future viewing. The webinar's date, time, and registration information will be made available on the following web page: *www.fs.usda.gov/managing-land/fire/grants.* Cost-sharing requirements are mandated in the Infrastructure Investment and Jobs Act. Communities meeting the definition of underserved per Executive Order 13985 are eligible to request a waiver of match requirements.

Non-Discrimination Statement

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

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

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

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

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

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Authority: This solicitation is authorized pursuant to the Infrastructure Investment and Jobs Act (Pub. L. 117–58).

John Crockett,

Acting Deputy Chief,State and Private Forestry.

[FR Doc. 2022–16448 Filed 7–28–22; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i Advisory Committee

AGENCY: U.S. Commission on Civil Rights

ACTION: Announcement of meeting

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Hawai'i Advisory Committee to the Commission will convene by Zoom virtual platform on Tuesday, August 23, 2022, from 1:00 p.m. to 2:30 p.m. HST, to discuss potential civil rights topics to study.

DATES: Tuesday, August 23, 2022, from 1:00 p.m.–2:30 p.m. HST.

Zoom Link: *https://www.zoomgov.com/j/1606975943.*

FOR FURTHER INFORMATION CONTACT: Kayla Fagota, Designated Federal Officer (DFO) at *kfagota@usccr.gov* or by phone at (434) 515–2395.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the Zoom link above. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for this meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Kayla Fagota at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl0AAA.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above phone number or email address.

Agenda

I. Welcome and Roll Call
II. Introductions
III. Overview of Project Process; Concept Stage
IV. Discussion of Topic Choice
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16343 Filed 7–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Guam Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Guam Advisory Committee

(Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 9:00 a.m. ChST on Tuesday, August 16, 2022, (7:00 p.m. ET on Monday, August 15, 2022) to discuss civil rights concerns in the territory.

DATES: The meeting will take place on Tuesday, August 16, 2022, from 9:00 a.m.–10:30 a.m. ChST (Monday, August 15, 2022, from 7:00 p.m.–8:30 p.m. ET).

Link to Join (*Audio/Visual*): *https://tinyurl.com/yj8sz88r.*

Telephone (*Audio Only*): Dial (800) 360–9505 USA Toll Free; Access Code: 2764 425 4150.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *kfajota@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Guam Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Announcements and Updates
III. Approval of May 24, 2022, and June 21, 2022, Meeting Minutes
IV. Election of Vice-Chair
V. Discussion: Potential Project Ideas
VI. Next Steps
VII. Public Comment
VIII. Adjournment

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16293 Filed 7–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Virginia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Virginia Advisory Committee (Committee) will hold a web meeting via Zoom on Monday, September 12, 2022, at 2:00 p.m. Eastern Time. The purpose of the meeting is to discuss identified findings and recommendations from previous panels on police oversight and accountability in Virginia.

DATES: The meeting will be held on: Monday, September 12, 2022, at 2:00 p.m. Eastern Time

Online Registration: https://bit.ly/3PK6pN8.

Join by Phone: 1–551–285–1373 US; Meeting ID: 160 754 1541.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 1–202–618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number (audio only) or online registration link (audio/visual). An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Virginia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Announcements and Updates
IV. Discussion: Testimony from Previous Panels
V. Next Steps
VI. Public Comments
VII. Adjournment

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16288 Filed 7–28–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the South Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the South Dakota State Advisory Committee to the Commission will convene a meeting on Monday, August 8, 2022, at 3:30 p.m. (CT). The purpose of the meeting is to debrief after the committee's July briefing panel and continue planning future panels. The topic of study is voting rights and voting access in South Dakota.

DATES: Monday, August 8, 2022, at 3:30 p.m. (CT).

Public Web Conference Registration Link (video and audio): https://tinyurl.com/2p93tu84; password, if needed: USCCR–SD.

If Joining By Phone Only, Dial: 1–551–285–1373; Meeting ID: 161 950 2444#.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota at *kfajota@usccr.gov* or by phone at (202) 809–9618.

SUPPLEMENTARY INFORMATION: The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with conference details found through registering at the web link above. To request other accommodations, please email *kfajota@usccr.gov* at least 7 days prior to the meeting for which accommodations are requested.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Kayla Fajota at *kfajota@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Monday, August 8, 2022, from 3:30 p.m. (CT)

I. Welcome and Roll Call
II. Announcements and Updates
III. Approval of Minutes
IV. Planning Meeting: Debrief of July Panel on Voting Rights and Access in South Dakota and Discuss Future Briefing Panels on the Same Topic
V. Public Comment
VI. Next Steps
VII. Adjournment

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16284 Filed 7–28–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of briefing.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a briefing of the Texas Advisory Committee (Committee) to the Commission will be held from 10:00 a.m. to 3:30 p.m. (Central Time) Wednesday, August 10, 2022. The purpose of the briefing is for the Committee to hear testimony regarding mental health in the Texas Juvenile Justice System.

DATES: The briefing will be held on Wednesday, August 10, 2022, from 10:00 a.m. to 3:30 p.m. Central Time.

Location: Rice University, Moody Center for the Arts, Lois Chiles Studio, 6100 Main Street, Houston, TX 77005

FOR FURTHER INFORMATION CONTACT: Brooke Peery (DFO) at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make comments during the open comment periods. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery at *bpeery@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email.

Agenda

I. Panel 1 (10:00 a.m.–11:30 a.m.)
II. Public Comment (11:30 a.m.–12:00 p.m.)
III. Lunch Break (12:00 p.m.–1:30 p.m.)
IV. Panel 2 (1:30 p.m.–3:00 p.m.)
V. Public Comment (3:00 p.m.–3:30 p.m.)

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16290 Filed 7–28–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Iowa Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Iowa Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a meeting on Wednesday, August 31, 2022, at 2:00 p.m.–3:45 p.m. Central Time. The Committee will review their report draft on employment discrimination and administrative closures.

DATES: The meeting will take place on Wednesday, August 31, 2022, at 2:00 p.m. CT. *Online Registration* (Audio/Visual): *https://tinyurl.com/5f34bahd. Telephone* (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2762 206 8331.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, DFO, at *afortes@usccr.gov* or (202) 519–2938.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the

conference details found through registering at the web link above. To request additional accommodations, please email *afortes@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Iowa Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above email or street address.

Agenda

I. Welcome
II. Review Draft Report
III. Public Comment
IV. Next Steps
a. Continue to Review Draft Report
V. Adjournment

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16298 Filed 7–28–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Massachusetts Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a briefing of the Massachusetts Advisory Committee to the Commission will convene via web conference on Tuesday, August 2, 2022, from 10:00 a.m. to 1:00 p.m. (ET). The purpose of the briefing is to hear from additional panelists on civil asset forfeiture. The public will have an opportunity to make comments towards the conclusion of the briefing.

DATES: Tuesday, August 2, 2022, from 10:00 a.m. to approximately 1:00 p.m. (ET)

Webex Link: https://tinyurl.com/2jcsbkbb.

If Phone Only: dial, 1–800–360–9505; Access Code: 2760 066 0670#.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor at *ero@usccr.gov* or by phone at 202–921–2212.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided above for the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Barbara Delaviez at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at the *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Tuesday, August 2, 2022; 10:00 a.m. to 2:00 p.m. (ET)

1. Welcome and Roll call
2. Chair Remarks
3. Briefing; Civil Asset Forfeiture in Boston
4. Public Comment
5. Other Business
6. Adjourn

Dated: July 26, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–16285 Filed 7–28–22; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–093]

Refillable Stainless Steel Kegs From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2019–2020; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notice in the **Federal Register** of July 8, 2022, in which Commerce announced the final results of the 2019–2020 administrative review of the antidumping duty (AD) order on refillable stainless steel kegs (kegs) from the People's Republic of China (China). This notice contained incorrect assessment and cash deposit rates for the China-wide entity.

FOR FURTHER INFORMATION CONTACT: Konrad Ptaszynski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6187.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of July 8, 2022, in FR Doc 2022–14566, on page 40785, in the second column, correct the second paragraph of the ''Assessment Rates'' caption to state the correct assessment rate of 63.60 percent for the China-wide entity. Also on page 40785, in the third column, correct the first paragraph of the ''Cash Deposit Requirements'' caption to state the correct cash deposit rate of 63.60 percent for the China-wide entity.

Background

On July 8, 2022, Commerce published in the **Federal Register** the final results of the 2019–2020 administrative review of the AD order on kegs from China.[1] Under the ''Assessment Rates'' section, we incorrectly stated the assessment rate of 77.13 percent for the China-wide entity. We also incorrectly stated the cash deposit rate of 77.13 percent for the China-wide entity in the ''Cash Deposit Requirements'' section. The 77.13

[1] *See Refillable Stainless Steel Kegs from the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2019–2020,* 87 FR 40784 (July 8, 2022).

percent rate should instead state the correct assessment and cash deposit rate of 63.60 percent for the China-wide entity.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(l), 751(a)(2)(B), and 777(i) of the Tariff Act of 1930, as amended.

Dated: July 25, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

[FR Doc. 2022–16310 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from Zhejiang Yuhua Timber Co. Ltd. (Yuhua), A-Timber Flooring Company Limited (A-Timber), and Mullican Flooring Co. (Mullican) (collectively, Yuhua *et al.*), the U.S. Department of Commerce (Commerce) is issuing these preliminary results of the changed circumstances review (CCR) of the antidumping duty (AD) order on multilayered wood flooring (MLWF) from the People's Republic of China (China). Commerce preliminarily determines that the MLWF sold through A-Timber and described below is produced and exported by Yuhua; as such, it is excluded from the AD order. We invite interested parties to comment on these preliminary results.

DATES: Applicable July 29, 2022.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin or Max Goldman, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6478 or (202) 482–3896, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2011, Commerce published the *Order.*[1] On September 1, 2021, Yuhua, a Chinese producer and exporter of MLWF, A-Timber, an unaffiliated company through which Yuhua's MLWF is sold to the United States, and Mullican, an unaffiliated U.S. importer of this MLWF, requested that Commerce initiate an expedited CCR, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), 19 CFR 351.216 and 351.221(c)(3).[2] In this CCR Request, Yuhua *et al.* requested that Commerce ''clearly state and provide clarifying instruction to U.S. Customs and Border Protection (CBP) that {MLWF} produced by {Yuhua} and sold to {Mullican} by A-Timber Flooring is excluded from the {*Order*}.'' [3]

According to Yuhua *et al.,* in the underlying less-than-fair-value investigation of MLWF from China, Yuhua, a mandatory respondent, reported that during the period of investigation (POI), it produced MLWF in China and engaged A-Timber as its sales agent. Yuhua *et al.* stated that A-Timber conducted all sales negotiations with unaffiliated U.S. customers and issued the invoices, and, upon confirmation of the sale, Yuhua exported the MLWF from China for delivery to the U.S. customers.[4] Based on this sales channel that Commerce examined in the investigation, Commerce calculated a dumping margin of zero percent for subject merchandise produced and exported by Yuhua which was sold to the United States through A-Timber, and excluded subject merchandise produced and exported by Yuhua from the *Order.* In their CCR Request, Yuhua *et al.* claim that the sales channel on which Commerce based the *Final Determination* has not changed since the POI.[5] However, starting in late 2020, CBP ceased implementing the cash deposit instructions issued by Commerce with respect to the *Final Determination,* which excluded from the *Order* MLWF produced and exported by Yuhua.[6] According to Yuhua *et al.,* CBP is now demanding the posting of cash deposits and requiring the entry of Yuhua's MLWF to be classified as ''Type 3'' entries subject to ADs.[7]

In its CCR Request, Yuhua *et al.* argue that Commerce intended to exclude from the *Order* MLWF produced and exported by Yuhua and sold through A-Timber, as Commerce determined that Yuhua was the ''exporter'' for such sales. Yuhua *et al.* argue that any other interpretation would mean that that Commerce was ''applying the zero rate to a company (Yuhua) that had not issued one invoice or made one sale to the U.S. during the POI.'' [8] Accordingly, Yuhua *et al.* now seek clarification that any MLWF sales transaction where Yuhua is the producer and exporter, as listed in the shipping documents, and where A-Timber is the sales agent, is excluded from the *Order.*[9]

On October 14, 2021, the American Manufacturers of Multilayered Wood Flooring (the petitioner) filed a letter in support of Yuhua *et al.'s* CCR Request, stating that Commerce should confirm that MLWF sold through Yuhua's ''sales agent, A-Timber . . . is excluded from the *Order,* consistent with {Commerce}'s prior determination . . . .'' [10] On October 15, 2021, Commerce extended the deadline to initiate this CCR and, on December 2, 2021, Commerce initiated this CCR, noting that it was not combining the initiation with the preliminary results because it was necessary to solicit additional information from Yuhua *et al.* regarding A-Timber's role in the sales channel of MLWF produced and exported by Yuhua.[11] On February 22, 2022, Yuhua *et al.* responded to Commerce's post-initiation questionnaire.[12] In its questionnaire response, Yuhua *et al.* reported, *inter alia,* the following information:

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[1] *See Multilayered Wood Flooring from the People's Republic of China: Amended Final Affirmative Determination of Sales at Less than Fair Value and Antidumping Duty Order,* 76 FR 76690 (December 8, 2011), as amended in *Multilayered Wood Flooring from the Peoples Republic of China: Amended Antidumping and Countervailing Duty Orders,* 77 FR 5484 (February 3, 2012) (collectively, the *Order*).

[2] *See* Yuhua *et al.'s* Letter, ''Request for Changed Circumstances Review on Multi-Layered Wood Flooring,'' dated September 1, 2021 (CCR Request).

[3] *Id.* at 1–2.

[4] *Id.* at 4 and Exhibit 2; *see also Multilayered Wood Flooring from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 76 FR 34318 (October 18, 2011) (*Final Determination*), and accompanying Issues and Decision Memorandum.

[5] *Id.* at 5.

[6] *Id.* at 2 and Exhibit 2 (Investigation CBP Cash Deposit Instructions). Yuhua *et al.* also notes that it requested a scope ruling regarding its reported sales channel, which Commerce rejected. *Id.* at Exhibit 1.

[7] *Id.* at 3.

[8] *Id.* at 7–8.

[9] *Id.* at 7 and Exhibit 2 (containing sample sales documents from Yuhua's response to section A of the AD questionnaire issued in the investigation).

[10] *See* Petitioner's Letter, ''Multilayered Wood Flooring from the People's Republic of China: Letter in Support of Request for Changed Circumstances Review,'' dated October 14, 2021.

[11] *See* Commerce's Letter, ''Request for a Changed Circumstance Review Antidumping Duty Order on Multilayered Wood Flooring from the People's Republic of China: Extension of Initiation Deadline,'' dated October 15, 2021; and *Multilayered Wood Flooring from the People's Republic of China: Notice of Initiation of Changed Circumstances Review,* 86 FR 68475 (December 2, 2021).

[12] *See* Yuhua *et al.'s* Letter, ''Supplemental Questionnaire Response,'' dated February 22, 2022.

• Yuhua sells MLWF to the United States exclusively through A-Timber and A-Timber conducts the marketing and price negotiations. Yuhua provides A-Timber U.S. sales targets and Yuhua and A-Timber strategize sales prices to the United States.
• The MLWF sold through A-Timber to the United States must be produced by Yuhua.
• A-Timber represents Yuhua at sales exhibitions where both Yuhua's and A-Timber's names are displayed on the information booths. A-Timber also represents Yuhua's ''Parrot Brand'' trademark.
• Mullican frequently visits Yuhua's factory and Yuhua promotes its products directly to Mullican.
• Yuhua is the exporter of record (*e.g.,* it is listed in the shipping documents) and ships directly to U.S. customers from its plant. A-Timber does not take title to the merchandise.
• The sales contract is between A-Timber and Mullican.
• Yuhua issues an invoice to A-Timber, and A-Timber adds a markup and issues its own sales invoice to Mullican.[13]

Scope of the Order

Multilayered wood flooring is composed of an assembly of two or more layers or plies of wood veneer(s)[14] in combination with a core.[15] The several layers, along with the core, are glued or otherwise bonded together to form a final assembled product. Multilayered wood flooring is often referred to by other terms, *e.g.,* ''engineered wood flooring'' or ''plywood flooring.'' Regardless of the particular terminology, all products that meet the description set forth herein are intended for inclusion within the definition of subject merchandise.

All multilayered wood flooring is included within the definition of subject merchandise, without regard to: dimension (overall thickness, thickness of face ply, thickness of back ply, thickness of core, and thickness of inner plies; width; and length); wood species used for the face, back and inner veneers; core composition; and face grade. Multilayered wood flooring included within the definition of subject merchandise may be unfinished (*i.e.,* without a finally finished surface to protect the face veneer from wear and tear) or ''prefinished'' (*i.e.,* a coating applied to the face veneer, including, but not exclusively, oil or oil-modified or water-based polyurethanes, ultra-violet light cured polyurethanes, wax, epoxy-ester finishes, moisture-cured urethanes and acid-curing formaldehyde finishes). The veneers may be also soaked in an acrylic-impregnated finish. All multilayered wood flooring is included within the definition of subject merchandise regardless of whether the face (or back) of the product is smooth, wire brushed, distressed by any method or multiple methods, or hand-scraped. In addition, all multilayered wood flooring is included within the definition of subject merchandise regardless of whether or not it is manufactured with any interlocking or connecting mechanism (for example, tongue-and-groove construction or locking joints). All multilayered wood flooring is included within the definition of the subject merchandise regardless of whether the product meets a particular industry or similar standard.

The core of multilayered wood flooring may be composed of a range of materials, including but not limited to hardwood or softwood veneer, particleboard, medium-density fiberboard, high-density fiberboard (HDF), stone and/or plastic composite, or strips of lumber placed edge-to-edge.

Multilayered wood flooring products generally, but not exclusively, may be in the form of a strip, plank, or other geometrical patterns (*e.g.,* circular, hexagonal). All multilayered wood flooring products are included within this definition regardless of the actual or nominal dimensions or form of the product. Specifically excluded from the scope are cork flooring and bamboo flooring, regardless of whether any of the sub-surface layers of either flooring are made from wood. Also excluded is laminate flooring. Laminate flooring consists of a top wear layer sheet not made of wood, a decorative paper layer, a core-layer of HDF, and a stabilizing bottom layer.

Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (HTSUS): [16] 4412.31.0520; 4412.31.0540; 4412.31.0560; 4412.31.0620; 4412.31.0640; 4412.31.0660; 4412.31.2510; 4412.31.2520; 4412.31.2610; 4412.31.2620; 4412.31.3175; 4412.31.4040; 4412.31.4050; 4412.31.4060; 4412.31.4070; 4412.31.4075; 4412.31.4080; 4412.31.4140; 4412.31.4160; 4412.31.4175; 4412.31.5125; 4412.31.5135; 4412.31.5155; 4412.31.5165; 4412.31.5175; 4412.31.5225; 4412.31.6000; 4412.31.9100; 4412.32.0520; 4412.32.0540; 4412.32.0560; 4412.32.0565; 4412.32.0570; 4412.32.0640; 4412.32.0665; 4412.32.2510; 4412.32.2520; 4412.32.2525; 4412.32.2530; 4412.32.2610; 4412.32.2625; 4412.32.3125; 4412.32.3135; 4412.32.3155; 4412.32.3165; 4412.32.3175; 4412.32.3185; 4412.32.3225; 4412.32.5600; 4412.32.5700; 4412.39.1000; 4412.39.3000; 4412.39.4011; 4412.39.4012; 4412.39.4019; 4412.39.4031; 4412.39.4032; 4412.39.4039; 4412.39.4051; 4412.39.4052; 4412.39.4059; 4412.39.4061; 4412.39.4062; 4412.39.4069; 4412.39.5010; 4412.39.5030; 4412.39.5050; 4412.94.1030; 4412.94.1050; 4412.94.3105; 4412.94.3111; 4412.94.3121; 4412.94.3131; 4412.94.3141; 4412.94.3160; 4412.94.3171; 4412.94.4100; 4412.94.5100; 4412.94.6000; 4412.94.7000; 4412.94.8000; 4412.94.9000; 4412.94.9500; 4412.99.0600; 4412.99.1020; 4412.99.1030; 4412.99.1040; 4412.99.3110; 4412.99.3120; 4412.99.3130; 4412.99.3140; 4412.99.3150; 4412.99.3160; 4412.99.3170; 4412.99.4100; 4412.99.5100; 4412.99.5105; 4412.99.5115; 4412.99.5710; 4412.99.6000; 4412.99.7000; 4412.99.8000; 4412.99.9000; 4412.99.9500; 4418.71.2000; 4418.71.9000; 4418.72.2000; 4418.72.9500; 4418.74.2000; 4412.59.6000, 4412.59.7000, 4412.59.8000, 4412.59.9000, 4412.59.9500, 4412.91.0600, 4412.91.1030, 4412.91.1040, 4412.91.3110, 4412.91.3120, 4412.91.3130, 4412.91.3140, 4412.91.3160, 4412.91.3170, 4412.91.5105, 4412.92.0700, 4412.92.1130, 4412.92.1140, 4412.92.3120, 4412.92.3160, 4412.92.3170, 4412.92.4200, 4412.92.5205, 4412.99.5800, 4412.99.6100, 4412.99.7100, 4412.99.8100, 4412.99.9100, 4412.99.9700, 4418.74.2000, 4412.74.9000, 4418.75.4000, and 4418.75.7000. *See* Memoranda ''Request from Customs and Border Protection to Update the ACE AD/CVD Case Reference File,'' dated October 31, 2018; and ''Request from Customs and Border Protection to Update the ACE AD/CVD Case Reference File,'' dated March 10, 2022.

[13] *Id.*

[14] A ''veneer'' is a thin slice of wood, rotary cut, sliced or sawed from a log, bolt or flitch. Veneer is referred to as a ply when assembled.

[15] Commerce Interpretive Note: Commerce interprets this language to refer to wood flooring products with a minimum of three layers.

[16] On October 31, 2018 and March 10, 2022, we added the following HTSUS subheadings to update the ACE Case Reference File: 4412.33.0640, 4412.33.0665, 4412.33.0670, 4412.33.2625, 4412.33.2630, 4412.33.3225, 4412.33.3235, 4412.33.3255, 4412.33.3275, 4412.33.3285, 4412.33.5700, 4412.34.2600, 4412.34.3225, 4412.34.3235, 4412.34.3255, 4412.34.3275, 4412.34.3285, 4412.34.5700, 4412.51.1030, 4412.51.1050, 4412.51.3105, 4412.51.4100, 4412.51.5100, 4412.52.1030, 4412.52.1050, 4412.52.3105, 4412.52.4100, 4412.52.5100,

4418.74.9000; 4418.75.4000; 4418.75.7000; 4418.79.0100; and 9801.00.2500.

While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Preliminary Results of Changed Circumstances Reviews

Commerce's *Final Determination* specified that entries produced and exported by Yuhua are excluded from the *Order*.[17] After reviewing the information on the record of this CCR, *e.g.,* that Yuhua *et al.'s* sales channel has not changed from that which we examined in the investigation, Commerce preliminarily determines that Yuhua is the producer and exporter of MLWF sold to the United States through A-Timber.

Should we reach the same determination in the final results, we will instruct CBP that, because Yuhua is the producer and exporter of MLWF sold through A-Timber, Yuhua's exclusion from the *Order* applies to entries of such merchandise. That is, the exclusion would not apply to MLWF produced and/or exported by a Chinese entity other than Yuhua and sold through A-Timber. We also preliminarily determine that it is appropriate to terminate any suspension of liquidation on MLWF produced and exported by Yuhua and sold through A-Timber, and retroactively apply this determination to all unliquidated entries of such merchandise. We intend to release draft CBP instructions to parties at the same time as these preliminary results and allow a period of time for comments.

Public Comment

Interested parties may submit case briefs not later than 14 days after the date of publication of this notice.[18] Rebuttal briefs, which must be limited to issues raised in case briefs, may be filed not later than seven days after the due date for case briefs.[19] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the deadlines set forth in this notice.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to the issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request must be received successfully in its entirely by 5:00 p.m. Eastern Time within 14 days of publication of this notice.[20] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[21] Parties should confirm the date, time and location of the hearing by telephone two days before the scheduled date.

Unless extended, consistent with 19 CFR 351.216(e), we intend to issue the final results of this CCR no later than 270 days after the date on which this review was initiated.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i)(1) of the Act, and 19 CFR 351.216 and 351.221(c)(3)(i).

Dated: July 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–16308 Filed 7–28–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813]

Citric Acid and Certain Citrate Salts From Belgium: Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 13, 2022, the U.S. Department of Commerce (Commerce) published the notice of initiation and preliminary results of the changed circumstances review (CCR) of the antidumping duty (AD) order on citric acid and certain citrate salts (citric acid) from Belgium. Commerce preliminarily determined that Citribel nv (Citribel) is the successor-in-interest to S.A. Citrique Belge N.V. (Citrique Belge) and, as a result, should be accorded the same AD cash deposit treatment as Citrique Belge with respect to subject merchandise. For these final results, Commerce continues to find that Citribel is the successor-in-interest to Citrique Belge and is entitled to the same cash deposit treatment as Citrique Belge under the AD order on citric acid from Belgium.

DATES: Applicable July 29, 2022.

FOR FURTHER INFORMATION CONTACT: Deborah Cohen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4521.

SUPPLEMENTARY INFORMATION:

Background

On June 13, 2022, Commerce published the *Initiation and Preliminary Results* [1] of this CCR, finding that Citribel is the successor-in-interest to Citrique Belge and, as such, that Citribel is entitled to Citrique Belge's AD cash deposit rate with respect to entries of subject merchandise.[2] In the *Initiation and Preliminary Results,* we provided all interested parties with an opportunity to comment and request a public hearing regarding our preliminary results. No party requested a hearing, submitted a case brief, or otherwise commented on the *Initiation and Preliminary Results.*

Scope of the Order [3]

The merchandise covered by this *Order* includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the

[17] *See* CCR Request at Exhibit 2 (Investigation CBP Cash Deposit Instructions).

[18] Commerce is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for filing of case briefs.

[19] Commerce is exercising its discretion under 19 CFR 351.309(d)(1) to alter the time limit for filing of rebuttal briefs.

[20] *See* 19 CFR 351.310(c).

[21] *See* 19 CFR 351.310(d).

[1] *See Citric Acid and Certain Citrate Salts from Belgium: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 87 FR 35738 (June 13, 2022) (*Initiation and Preliminary Results*).

[2] *Id.*

[3] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Final Results of Changed Circumstances Review

Having received no comments from interested parties and finding no information or evidence on the record that calls into question the preliminary results, we continue to find that Citribel is the successor-in-interest to Citrique Belge and, as such, that Citribel is entitled to Citrique Belge's AD cash deposit rate with respect to entries of subject merchandise for the reasons stated in the *Initiation and Preliminary Results.*[4] As a result of this determination and consistent with established practice, we find that Citribel should receive the AD cash deposit rate previously assigned to Citrique Belge. Consequently, Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced and/or exported by Citribel and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at the AD cash deposit rate in effect for Citrique Belge. This cash deposit requirement shall remain in effect until further notice.

[4] *Initiation and Preliminary Results.*

Administrative Protective Order

This notice serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e).

Dated: July 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–16306 Filed 7–28–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813]

Citric Acid and Certain Citrate Salts from Belgium: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that S.A. Citrique Belge N.V. (Citrique Belge) did not sell subject merchandise in the United States at prices below normal value during the July 1, 2020, through June 30, 2021, period of review (POR). We invite interested parties to comment on these preliminary results.

DATES: Applicable July 29, 2022.

FOR FURTHER INFORMATION CONTACT: David Lindgren and Deborah Cohen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1671 and 202–482–4521, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2018, Commerce published the antidumping duty (AD) order on citric acid and certain citrate salts (citric acid) from Belgium in the **Federal Register**.[1] On September 7, 2021, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an AD administrative review of the *Order*.[2] During the course of this administrative review, Citrique Belge responded to Commerce's questionnaire and supplemental questionnaires. On March 8, 2022, Commerce extended the deadline for issuing the preliminary results of this review.[3] For further details, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise covered by this *Order* includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Export price has been calculated in accordance with section 772(a) of the Act and normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed at

[1] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 50034 (September 7, 2021).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated March 8, 2022.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Citric Acid and Certain Citrate Salts from Belgium; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

https://access.trade.gov/public/FRNoticesListLayout.aspx.

Preliminary Results of the Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period July 1, 2020, through June 30, 2021:

Exporter/producer	Estimated weighted-average dumping margin (percent)
S.A. Citrique Belge N.V	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in these preliminary results to parties in this proceeding within five days of the date of publication of this notice.[5] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[6] Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument: (1) a statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.[7] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS. Note that Commerce has temporarily modified certain portions of its requirements for serving documents containing business proprietary information, until further notice.[8]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request must be received successfully in its entirely by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice in the **Federal Register**.[9] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[10] Parties should confirm the date, time and location of the hearing by telephone two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised in any the written briefs, no later than 120 days after the date of publication of this notice, unless otherwise extended.[11]

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If the weighted-average dumping margin for Citrique Belge (*i.e.,* the sole individually-examined respondent in this review) is not zero or *de minimis* (*i.e.,* greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of the review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[12] If Citrique Belge's weighted-average dumping margin is zero or *de minimis* in the final results of the review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [13]

For entries of subject merchandise during the POR produced by Citrique Belge for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction.[14]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Citrique Belge [15] will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent, and therefore *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 19.30 percent, the rate established in the less-than-fair-value investigation of this proceeding.[16] These cash deposit requirements, when imposed, shall remain in effect until further notice.

[5] *See* 19 CFR 351.224(b).

[6] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[7] *See* 19 CFR 351.309(c)(2) and (d)(2); *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See Temporary Rule.*

[9] *See* 19 CFR 351.310(c).

[10] *See* 19 CFR 351.310(d).

[11] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

[12] *See* 19 CFR 351.106(c)(2).

[13] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[14] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[15] On June 13, 2022, Commerce preliminarily determined that Citribel nv (Citribel) is the successor-in-interest to Citrique Belge. *See Citric Acid and Certain Citrate Salts from Belgium: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 87 FR 35738 (June 13, 2022). Should Commerce's final results in the changed circumstances review remain unchanged from these preliminary results, we intend to instruct CBP to assign entries of subject merchandise produced and/or exported by Citribel the AD cash deposit rate applicable to Citrique Belge. *Id.*

[16] *See Order,* 83 FR at 35215.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(1).

Dated: July 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2022–16305 Filed 7–28–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–051, C–570–052]

Certain Hardwood Plywood Products From the People's Republic of China: Preliminary Scope Determination and Affirmative Preliminary Determination of Circumvention of the Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain hardwood plywood products and veneered panels (hardwood plywood) exported from the Socialist Republic of Vietnam (Vietnam), which were assembled in Vietnam using hardwood plywood inputs sourced from the People's Republic of China (China) are products of China and are subject to the antidumping duty (AD) and countervailing duty (CVD) orders on hardwood plywood from China. Additionally, Commerce preliminarily determines that certain hardwood plywood assembled in Vietnam using hardwood plywood inputs sourced from China are circumventing the AD and CVD orders on hardwood plywood from China.

DATES: Applicable July 29, 2022.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2593.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2018, Commerce issued the *Orders* on imports of hardwood plywood from China.[1] On February 25, 2020, the Coalition for Fair Trade in Hardwood Plywood (the petitioner) alleged that imports of hardwood plywood that was assembled in Vietnam using core veneers, multi-ply core veneered panels, and/or veneer core platforms sourced from China are circumventing the *Orders.*[2] In their allegation, the petitioner requested that Commerce issue a scope ruling that certain hardwood plywood completed in Vietnam using hardwood plywood inputs manufactured in China, and imported into the United States as Vietnamese-origin plywood is within the scope of the *Orders.* In the alternative, the petitioner requested that Commerce initiate an anti-circumvention inquiry, pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h),[3] to determine whether these products constitute merchandise completed or assembled in a third country that is circumventing, and should be included within, the scope of the *Orders.*

On June 17, 2020, Commerce published in the **Federal Register** the notice of initiation of these scope and anti-circumvention inquiries.[4] In that notice Commerce explained that it intended to examine the scope inquiry request filed by the petitioner under 19 CFR 351.225(c) as part of this anti-circumvention inquiry, and that we will make a final finding with regard to the scope inquiry to determine whether any of the production scenarios identified by the petitioner are already properly considered subject to the scope of the *Orders.*[5]

On April 15, 2022, Commerce extended the deadline to issue a final determination in these inquiries to October 17, 2022.[6] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[7] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Orders

The products subject to these *Orders* are hardwood and decorative plywood, and certain veneered panels. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Merchandise Subject to the Scope and Anti-Circumvention Inquiries

These scope and anti-circumvention inquiries cover hardwood plywood

[1] *See Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 83 FR 504 (January 4, 2018); and *Certain Hardwood Plywood Products from the People's Republic of China: Countervailing Duty Order,* 83 FR 513 (January 4, 2018) (collectively, the *Orders*).

[2] *See* Petitioner's Letter, ''Certain Hardwood Plywood Products from The People's Republic of China: Request from Scope Ruling/Anti-Circumvention ruling,'' dated February 25, 2020 (Petitioner's Request).

[3] Commerce significantly revised its scope regulations on September 20, 2021, with an effective date of November 4, 2021. *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021). The amendments to 19 CFR 351.225 apply to scope inquiries for which a scope ruling application is filed, as well as any scope inquiry self-initiated by Commerce, on or after November 4, 2021. The newly promulgated 19 CFR 351.226 applies to circumvention inquiries for which a circumvention request is filed, as well as any circumvention inquiry self-initiated by Commerce, on or after November 4, 2021. We note that these scope and circumvention inquiries were initiated prior to the effective date of the new regulations, and, thus, any reference to the regulations is to the prior version of the regulations.

[4] *See Certain Hardwood Plywood Products from the People's Republic of China: Initiation of Anti-circumvention Inquiries and Scope Inquiries on the Antidumping Duty and Countervailing Duty Orders; Vietnam Assembly,* 85 FR 36530 (June 17, 2020) (*Initiation Notice*).

[5] *Id.,* 85 FR at 36533.

[6] *See* Memorandum, ''Extension of Deadline,'' dated April 18, 2022.

[7] *See* Memorandum, ''Preliminary Decision Memorandum for the Anti-Circumvention and Scope Inquiries on the Antidumping Duty and Countervailing Duty Orders on Certain Harwood Plywood Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

exported to the United States that was completed in Vietnam using: (1) face/back veneers and assembled core components (*e.g.,* veneer core platforms) manufactured in China; (2) fully assembled veneer core platforms manufactured in China and face/back veneer produced in Vietnam or third countries; (3) multi-ply panels of glued core veneers manufactured in China and combined in Vietnam to produce veneer core platforms and combined with either face and/or back veneer produced in China, Vietnam, or a third country; (4) face/back veneers and individual core veneers produced in China; and (5) individual core veneers manufactured in China and processed into a veneer core platform [8] in Vietnam and combined with face/back veneer produced in Vietnam or a third country.

Scope Determination

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that hardwood plywood produced under three of the five production scenarios that are subject to these inquiries are covered by the scope of the *Orders.* Specifically, these in-scope products include hardwood plywood exported to the United States that is composed of: (1) face veneer, back veneer, and assembled core components (*e.g.,* veneer core platforms) manufactured in China and assembled in Vietnam; (2) fully assembled veneer core platforms manufactured in China that are combined in Vietnam with face and/or back veneers produced in Vietnam or third countries; and (3) multi-ply panels of glued core veneers manufactured in China that are combined in Vietnam to produce veneer core platforms and combined with either a face and/or back veneer produced in China, Vietnam, or a third country. In reaching this determination we relied, in part, on our recent Finewood Scope Ruling, in which we determined that the country of origin of plywood is imparted at the location where the veneers are first glued/assembled,[9] as well as additional record evidence and analysis.[10]

As a result, we preliminarily determine that this merchandise is within the *Orders* and will instruct U.S. Customs and Border Protection (CBP) to suspend entries of hardwood plywood from Vietnam, which were assembled in Vietnam under the three production scenarios above. To administer this preliminary affirmative scope determination, exporters and importers of hardwood plywood completed in Vietnam using non-Chinese origin hardwood plywood inputs will be permitted to certify that the exported products were not produced under any of the three scenarios that result in subject merchandise. If an importer files such certifications, it will be required to maintain those certifications and supporting documentation to provide to CBP and/or Commerce upon request.[11] Properly certified entries are not subject to AD and CVD duties under the *Orders.* Exemption from AD and CVD duties under the *Orders* is permitted only if the certification and documentation requirements specified in Appendix II are met.

Affirmative Preliminary Determination of Circumvention

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that products produced under the remaining two of the five production scenarios that are subject to these inquiries are circumventing the *Orders.* Specifically, these products include hardwood plywood exported to the United States that was assembled in Vietnam and composed of: (1) face/back veneers and individual core veneers produced in China; and (2) individual core veneers manufactured in China and processed into a veneer core platform in Vietnam and combined with face/back veneer produced in Vietnam or a third country.

As a result, we preliminarily determine that it is also appropriate to include this merchandise within the *Orders* and to instruct CBP to suspend entries of hardwood plywood from Vietnam, which were assembled in Vietnam under the two production scenarios above. To administer this preliminary affirmative determination of circumvention, exporters and importers of hardwood plywood completed in Vietnam using non-Chinese origin hardwood plywood inputs will be permitted to certify that the exported products were not produced under either of the two scenarios that result in merchandise circumventing the *Orders.* As noted above, if an importer files such certifications, it will also be required to maintain the certifications and supporting documentation to provide to CBP and/or Commerce upon request.[12] Properly certified entries are not subject to AD and CVD duties under the *Orders.* Exemption from AD and CVD duties under the *Orders* is permitted only if the certification and documentation requirements specified in Appendix II are met.

Methodology

Commerce made these preliminary scope and circumvention findings in accordance with section 781(b) of the Act and 19 CFR 351.225(g). We relied on information placed on the record by the petitioner and the Government of Vietnam, and information we placed on the record. We also relied on the facts available under section 776(a) of the Act, including facts available with adverse inferences under section 776(b) of the Act, where appropriate.

In particular, we requested information from numerous companies in Vietnam in conducting these inquiries. While we received responses from the majority of these companies, 14 companies failed to respond to our initial questionnaire and/or a supplemental questionnaire and an additional 22 companies provided information that either contained significant discrepancies and inconsistencies or was misleading.[13] Therefore, we preliminarily find that these 36 companies withheld information, failed to provide information by the deadline or in the form and manner requested, and significantly impeded these inquiries. Thus, we find that they failed to cooperate to the best of their abilities; thereby, we have used adverse inferences when selecting from among the facts otherwise available on the record for certain aspects of this preliminary determination, pursuant to sections 776(a) and (b) of the Act. As adverse facts available, we have preliminarily determined that these 36 companies produce hardwood plywood under all five of the production scenarios subject to these inquiries. Additionally, we preliminarily determine that these 36 companies [14] are precluded from participating in the certification program we are establishing for applicable exports of

[8] A veneer core platform is defined as two or more wood veneers that form the core of an otherwise completed hardwood plywood product (*i.e.,* a hardwood plywood product to which the outer (face and back) veneers have not yet been affixed). *See* Petitioner's Request at Exhibit 11.

[9] *See* Memorandum, ''Placing Documents Relevant to this Proceeding on the Record,'' dated February 18, 2022, at Attachment (Memorandum, ''Antidumping Duty and Countervailing Duty Orders on Certain Hardwood Plywood Products from the People's Republic of China, Enforcement and Protect Act (EAPA) Investigation No. 7252: Final Scope Ruling,'' dated January 21, 2022 (Finewood Scope Ruling)).

[10] *See* Preliminary Decision Memorandum.

[11] The importer certification is provided at Appendix III and the exporter certification is provided at Appendix IV.

[12] The importer certification is provided at Appendix III and the exporter certification is provided at Appendix IV.

[13] *See* Appendix V for a list of companies that either failed to respond to our requests for information or provided unreliable information.

[14] *Id.*

hardwood plywood from Vietnam. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Suspension of Liquidation

In accordance with 19 CFR 351.225(l)(2), for entries of hardwood plywood from Vietnam that were produced under any of the three production scenarios that we preliminarily determined are subject merchandise, Commerce will instruct CBP to continue to suspend liquidation and require a cash deposit of estimated duties, at the applicable rate, that are entered, or withdrawn from warehouse, for consumption on or after June 17, 2020, the date of publication of initiation of the scope inquiries in the **Federal Register**.[15] Similarly, for entries of hardwood plywood from Vietnam that were produced under either of the two production scenarios that we preliminarily determined are circumventing the *Orders,* and therefore should be included within the *Orders,* we will instruct CBP to suspend liquidation and require a cash deposit of estimated duties, at the applicable rates, that are entered, or withdrawn from warehouse, for consumption on or after June 17, 2020, the date of publication of initiation of the anti-circumvention inquiries in the **Federal Register**.[16]

Where companies subject to these inquiries have their own company-specific rate under the *Orders,* the cash deposit rate will be the company-specific rate. Otherwise, Commerce will instruct CBP to require AD cash deposits equal to the China-wide rate of 183.36 percent and CVD cash deposits equal to the all-others rate of 22.98 percent.

Hardwood plywood assembled in Vietnam under scenarios other than the five production scenarios identified above are not subject to these inquiries. Therefore, cash deposits are not required for such merchandise, subject to the following certification requirements.[17] Note that, as further described below, the 36 non-cooperative exporters listed in Appendix V are not eligible to participate in this certification program.[18]

If an importer of hardwood plywood assembled in Vietnam claims that the hardwood plywood was not produced using any of the Chinese hardwood plywood input scenarios subject to these inquiries, the importer and exporter must meet the certification and documentation requirements described in Appendix II. An exporter of hardwood plywood assembled in Vietnam claiming that its hardwood plywood was not produced using any of the Chinese hardwood plywood input scenarios subject to these inquiries must prepare and maintain an Exporter Certification and documentation supporting the exporter certification (*see* Appendix IV). In addition, importers of such hardwood plywood must prepare and maintain an importer certification (*see* Appendix III) as well as documentation supporting the importer certification. Besides the importer certification, the importer must also maintain a copy of the exporter certification (*see* Appendix IV), and relevant supporting documentation from its exporter of hardwood plywood assembled in Vietnam that was not produced using any of the Chinese hardwood plywood input scenarios subject to these inquiries.

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Commerce will notify interested parties of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline for case briefs.[19] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these scope and anti-circumvention inquiries are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[20]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to these anti-circumvention inquiries within the *Orders.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the inquiry merchandise. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f) and (h).

Dated: July 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Orders*
IV. Merchandise Subject to the Scope and Anti-Circumvention Inquiries
V. Period of the Scope and Anti-Circumvention Inquiries
VI. Statutory Framework

[15] *See Initiation Notice.*

[16] *Id.*

[17] *See* Appendix II for the certification requirements and Appendix III for the importer certification.

[18] *See* Preliminary Decision Memorandum at ''Use of Facts Available with an Adverse Inference''; and, *e.g., Anti-circumvention Inquiry of the Antidumping Duty Order on Certain Pasta from Italy: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order,* 63 FR 18364, 18366 (April 15, 1998), unchanged in *Anti-Circumvention Inquiry of the Antidumping Duty Order on Certain Pasta from Italy: Affirmative Final Determination of Circumvention of the Antidumping Duty Order,* 63 FR 54672, 54675–76 (October 13, 1998).

[19] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[20] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

VII. Use of Facts Available with an Adverse Inference
VIII. Scope and Anti-Circumvention Determinations
IX. Country-Wide Determination
X. Certification Requirement
XI. Recommendation

Appendix II

Certification Requirements

If a company imports hardwood plywood from the Socialist Republic of Vietnam (Vietnam) and claims that the hardwood plywood was completed in Vietnam using a production scenario other than those subject to these inquiries, the importer is required to complete and maintain the importer certification, attached as Appendix III, and retain all supporting documentation. The importer is further required to maintain a copy of the exporter certification, attached as Appendix IV, and retain all supporting documentation. The importer certification must be completed, signed, and dated by the time of filing of the entry summary for the relevant importation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry summary number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation (*e.g.,* invoice, purchase order, production records, *etc.*). The exporter certification must be completed, signed, and dated by the time of shipment of the relevant entries (except as noted below). The exporter certification should be completed by the party selling the subject merchandise manufactured in Vietnam to the United States.

The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process. However, the importer and exporter will be required to present the certifications, and supporting documentation, to the Department of Commerce and/or U.S. Customs and Border Protection (CBP), as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications and supporting documentation for the later of: (1) a period of five years from the date of entry; or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

For hardwood plywood completed in Vietnam under the two production scenarios subject to these inquiries that we have found to be circumventing the *Orders,* Commerce has established the following third-country case numbers in the Automated Commercial Environment (ACE): A–552–006 and C–552–007.

If it is determined that the certification and/or documentation requirements in a certification have not been met, Commerce intends to instruct CBP to suspend, under the antidumping duty (AD) and countervailing duty (CVD) *Orders*[21] on hardwood plywood from the People's Republic of China, A–570–051/C–570–052 or A–552–006/C–552–007, all unliquidated entries for which these requirements were not met and require the importer to post applicable AD and CVD cash deposits equal to the rates as determined by Commerce. Entries suspended under A–570–051/C–570–052 or A–552–006/C–552–007 will be liquidated pursuant to applicable administrative reviews of the *Orders* or through the automatic liquidation process.

For entries suspended pursuant to the preliminary determination of these scope and anti-circumvention inquiries that were shipped and/or entered, or withdrawn from warehouse, for consumption during the period, June 17, 2020 (the date of initiation of these scope and anti-circumvention inquiries) through the date of publication of the preliminary determination in the **Federal Register**, for which certifications are required, the exporter certifications should be completed as soon as practicable, but not later than 45 days after publication of the preliminary determination in the **Federal Register**. Accordingly, the relevant paragraph in the certification should be edited to reflect that the certification was completed within this time frame. Specifically, exporters should complete the language in paragraph G in the exporter certification that reads: ''The shipments/products referenced herein shipped before mm/dd/yyyy, the date on which Commerce published notice of its preliminary scope and anti-circumvention findings in the **Federal Register**. This certification was completed on mm/dd/yyyy, within 45 days of the **Federal Register** notice publication.'' For such entries, exporters each have the option to complete a blanket certification covering multiple entries, individual certifications for each entry, or a combination thereof. The exporter certifications should be maintained by both the importer and exporter and provided to CBP or Commerce only upon request by the respective agency. The exporter must provide the importer a copy of the exporter certification within 45 days of the publication of the preliminary determination in the **Federal Register**.

For unliquidated entries (and entries for which liquidation has not become final) of merchandise entered as non-AD/CVD type entries (*e.g.* type 01) that were shipped and/or entered, or withdrawn from warehouse, for consumption in the United States during the period, June 17, 2020 (the date of initiation of these scope and anti-circumvention inquiries) through the date of publication of the preliminary determination in the **Federal Register**, manufactured using any of the production scenarios subject to these inquiries, importers should file a Post Summary Correction with CBP, in accordance with CBP's regulations, regarding conversion of such entries from non-AD/CVD type entries to AD/CVD type entries (*e.g.,* type 01 to type 03). For such shipments, the exporter certifications should be completed as soon as practicable, but not later than 45 days after publication of the preliminary determination in the **Federal Register**. Importers should report those AD/CVD type entries that were produced under production scenarios 1, 2, or 3, which we have found to be covered by the scope of the *Orders,* under the case numbers for the *Orders* on hardwood plywood from the People's Republic of China, A–570–051/C–570–052. Importers should report those AD/CVD type entries that were produced under production scenarios 4 or 5, which we have found to be circumventing the *Orders,* using the third-country case numbers, A–552–006/C–552–007. Similarly, the importer should pay cash deposits on those entries consistent with the regulations governing post summary corrections that require payment of additional duties.

[21] *See Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 83 FR 504 (January 4, 2018); and *Certain Hardwood Plywood Products from the People's Republic of China: Countervailing Duty Order,* 83 FR 513 (January 4, 2018) (collectively, the *Orders*).

Appendix III

IMPORTER CERTIFICATION

I hereby certify that:

(A) My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the hardwood plywood completed in Vietnam that entered under entry summary number(s), identified below, and are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have ''direct personal knowledge'' of the importation of the product (*e.g.,* the name of the exporter) in its records;

(C) I have personal knowledge of the facts regarding the production of the imported products covered by this certification. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the source of the hardwood plywood inputs used to produce the imported products);

(D) This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller:
Foreign Seller's Address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Country of Origin of core veneers/veneered panels/veneer core platforms:

(E) The hardwood plywood completed in Vietnam was not produced under any of the production scenarios subject to these certifications:

1. Face veneer, back veneer, and assembled core components (*e.g.,* veneer core platforms (see note below)) manufactured in China and assembled in Vietnam;

2. Fully assembled veneer core platforms manufactured in China that are combined in Vietnam with face and/or back veneers produced in Vietnam or third countries;

3. Multi-ply panels of glued core veneers manufactured in China that are combined in Vietnam to produce veneer core platforms and combined with either a face and/or back veneer produced in China, Vietnam, or a third country;

4. Face veneer, back veneer, and individual core veneers produced in China and assembled into hardwood plywood in Vietnam; and

5. Individual core veneers manufactured in China and processed into a veneer core platform in Vietnam and combined with a face and/or back veneer produced in Vietnam or other third country;

Note: A veneer core platform is defined as two or more wood veneers that form the core of an otherwise completed hardwood plywood product (*i.e.,* a hardwood plywood product to which the outer (face and back) veneers have not yet been affixed).

(F) I understand that {IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, certificates of origin, production records, invoices, USDA Plant and Plant Product Declaration Form *etc.*) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

(G) I understand that {IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

(H) I understand that {IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above) and supporting documentation, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

(I) I understand that {IMPORTING COMPANY} is required to maintain and provide a copy of the exporter's certification and supporting documentation, upon request, to CBP and/or Commerce;

(J) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

(K) I understand that failure to maintain the required certification and supporting documentation and/or failure to substantiate the claims made herein and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty orders on hardwood plywood from China. I understand that such finding will result in:

○ suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce; and

○ the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify that future imports of hardwood plywood are not produced under any of the production scenarios subject to these certifications.

(L) I understand that agents of the importer, such as brokers, are not permitted to make this certification;

(M) This certification was completed by the time of filing the entry summary or within 45 days of the date on which Commerce published notice of its preliminary scope and anti-circumvention findings in the **Federal Register**; and

(N) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{**NAME OF COMPANY OFFICIAL**}

{**TITLE**}

{**DATE**}

Appendix IV

EXPORTER CERTIFICATION

I hereby certify that:

(A) My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the production and exportation in the Customs territory of the United States of the hardwood plywood identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have ''direct personal knowledge'' of the producer's identity and location;

(C) The hardwood plywood completed in Vietnam was not produced under any of the following production scenarios:

1. Face veneer, back veneer, and assembled core components (*e.g.,* veneer core platforms (see note below) manufactured in China and assembled in Vietnam;

2. Fully assembled veneer core platforms manufactured in China that are combined in Vietnam with face and/or back veneers produced in Vietnam or third countries;

3. Multi-ply panels of glued core veneers manufactured in China that are combined in Vietnam to produce veneer core platforms and combined with either a face and/or back veneer produced in China, Vietnam, or a third country;

4. Face veneer, back veneer, and individual core veneers produced in China and assembled into hardwood plywood in Vietnam; and

5. Individual core veneers manufactured in China and processed into a veneer core platform in Vietnam and combined with a face and/or back veneer produced in Vietnam or other third country;

Note: A veneer core platform is defined as two or more wood veneers that form the core of an otherwise completed hardwood plywood product (*i.e.,* a hardwood plywood product to which the outer (face and back) veneers have not yet been affixed).

(D) This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:

Foreign Seller's Invoice to U.S. Customer Line item #:

Producer's Invoice # to Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

Producer's Invoice # Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

Name of core veneers/veneered panel/ veneer core platform producer:

(E) The hardwood plywood products covered by this certification were shipped to {NAME OF U.S. PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(F) I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, production records, invoices, *etc.*) for the later of: (1) a period of five years from the date of entry; or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

(G) I understand that {NAME OF EXPORTING COMPANY} must provide this Exporter Certification to the U.S. importer by the time of shipment. {Or}

The shipments/products referenced herein shipped before the mm/dd/yyyy, the date on which Commerce published notice of its preliminary scope and anti-circumvention findings in the **Federal Register**. This certification was completed on mm/dd/yyyy, within 45 days of the **Federal Register** notice publication;

(H) I understand that failure to maintain the required certification and supporting documentation, failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are within the scope of the antidumping (AD)/countervailing duty (CVD) orders on hardwood plywood from China. I understand that such a finding will result in:

(i) suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the requirement that the importer post applicable AD and/or CVD cash deposits (as appropriate) equal to the rates as determined by Commerce; and

(iii) the revocation of {NAME OF EXPORTING COMPANY}'s privilege to

certify that future imports of hardwood plywood are not produced under any of the production scenarios subject to these certifications.

(J) This certification was completed at time of shipment or within 45 days of the date on which Commerce published notice of its preliminary scope and anti-circumvention findings in the **Federal Register***;*

(K) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.
Signature

{**NAME OF COMPANY OFFICIAL**}

{**TITLE**}

{**DATE**}

Appendix V

Companies That Failed To Cooperate

1. An An Plywood Joint Stock Company
2. Arrow Forest International Co., Ltd
3. BAC Son Woods Processing Joint Stock Company
4. BHL Thai Nguyen Corp.
5. Eagle Industries Company Limited
6. Golden Bridge Industries Pte. Ltd.
7. Govina Investment Joint Stock Company
8. Greatriver Wood Co. Ltd.
9. Greatwood Hung Yen Joint Stock Company
10. Groll Ply and Cabinetry
11. Hai Hien Bamboo Wood Joint Stock Company
12. Her Hui Wood (Vietnam) Co., Ltd.
13. Hoang LAM Plywood Joint Stock Co.
14. Huong Son Wood Group Co., Ltd.
15. Innovgreen Thanh Hoa Co. Ltd.
16. Lechenwood Viet Nam Company Limited
17. Long LUU Plywood Production Co., Ltd.
18. Long Phat Construction Investment and Trade Joint Stock Company
19. Plywood Sunshine Ltd. Co.
20. Quang Phat Woods JSC
21. TEKCOM Corporation
22. Win Faith Trading

Companies That Failed To Respond

1. Bao Yen MDF Joint Stock Company
2. BHL Vietnam Investment and Development
3. Dong Tam Production Trading Company Limited
4. Greatwood Company Limited
5. Linwood Vietnam Co. Ltd
6. Quoc Thai Forestry Import Export Limited Company
7. Rongjia Woods Vietnam Company Limited
8. Sumec Huongson Wood Group Co. Ltd.
9. Tan Tien Co. Ltd
10. Thang Long Wood Panel Company Ltd.
11. Thanh Hoa Stone Export Company
12. Truong Son North Construction JSC
13. Vietind Co. Ltd.
14. Vietnam Golden Timber Company Limited

[FR Doc. 2022–16307 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–854]

Certain Steel Nails From Taiwan: Notice of Court Decision Not in Harmony With the Results of Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 15, 2022, the U.S. Court of International Trade (the Court or CIT) issued its final judgment in *Pro-Team Coil Nail Enter.* v. *United States,* Consol. Court No. 18–00027, Slip Op. 22–84 (*Pro-Team IV*), sustaining the U.S. Department of Commerce's (Commerce) remand results pertaining to the administrative review of the antidumping duty (AD) order on certain steel nails from Taiwan covering the period May 20, 2015, to June 30, 2016. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's *Final Results* of the administrative review, and that Commerce is amending the *Final Results* with respect to the dumping margin assigned to the mandatory respondent, PT Enterprise, Inc./Pro-Team Coil Nail Enterprise, Inc. and to the respondents that were not selected for individual examination (*i.e.,* the non-examined companies), Hor Liang Industrial Corp. and Romp Coil Nails Industries Inc.

DATES: Applicable July 25, 2022.

FOR FURTHER INFORMATION CONTACT: Erin Kearney or George McMahon, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0167 or (202) 482–1167, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 13, 2018, Commerce published its *Final Results* in the 2015–2016 AD administrative review of certain steel nails from Taiwan.[1] In this administrative review, Commerce selected three mandatory respondents for individual examination: PT Enterprise, Inc./Pro-Team Coil Nail Enterprise, Inc. (PT/Pro-Team); Unicatch Industrial Co., Ltd. (Unicatch); and Bonuts Hardware Logistics Co., LLC (Bonuts). Based on the mandatory respondents' failure to cooperate to the best of their abilities in responding to Commerce's requests for information, Commerce initially relied on the petition rate as adverse facts available (AFA) to determine the dumping rates for each of the mandatory respondents. Commerce assigned to the non-examined companies the dumping margin assigned to the mandatory respondents, 78.17 percent, in the *Final Results*.[2]

PT/Pro-Team and Unicatch challenged the application of AFA. Bonuts did not challenge the AFA rate it was assigned.[3]

In its *First Remand Order,* the Court sustained Commerce's use of facts available to determine the margin for Unicatch, but remanded two issues to Commerce: (1) the application of AFA to determine the AD margin of PT/Pro-Team; and (2) to explain the use of an adverse inference when using facts available to determine the AD margin of Unicatch.[4]

In its first remand redetermination issued on March 25, 2020, Commerce reconsidered its AFA determinations.[5] Commerce calculated a dumping margin for PT/Pro-Team that was *de minimis,* but continued to apply AFA to Unicatch.[6] Commerce used the AFA rate that it corroborated in the *Final Results* and recalculated the non-examined companies' rate using the ''expected method'' of averaging PT's and Unicatch's rates. Commerce calculated the non-examined companies' rate using a simple average of PT/Pro-Team's calculated zero percent margin and the 78.17 percent AFA rate applied to Unicatch.[7]

In the *Second Remand Order,* the Court sustained Commerce's calculation of a weighted-average dumping margin of zero percent for PT/Pro-Team and Commerce's application of a rate based on AFA for Unicatch.[8] The Court

[1] *See Certain Steel Nails from Taiwan: Final Results of Antidumping Duty Administrative Review and Partial Rescission of Administrative Review;* 2015–2016, 83 FR 6163 (February 13, 2018) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM).

[2] *Id.*

[3] *See Pro-Team Coil Nail Enter.* v. *United States* (*Pro-Team I*), 419 F. Supp. 3d 1319, 1323–25 (CIT 2019) (*First Remand Order*).

[4] *Id.*

[5] *See Final Results of Redetermination Pursuant to Court Remand, Pro-Team Coil Nail Enter.* v. *United States,* Consol. Court No. 18–00027, Slip Op. 19–169 (CIT December 19, 2019), dated March 25, 2020 (*First Redetermination*).

[6] Bonuts did not challenge the application of AFA to its company, and the AFA rate assigned to Bonuts has remained unchanged in this segment of the proceeding.

[7] *See First Redetermination* at 32.

[8] *See Pro-Team Coil Nail Enterprise, Inc.* v. *United States,* 483 F. Supp. 3d 1242 (CIT 2020) (*Second Remand Order*).

remanded Commerce's selection of the 78.17 percent rate applied as AFA, which the Court found Commerce did not adequately corroborate.[9] The Court also stated that ''Commerce largely ignored Unicatch's arguments that the 78.17 percent rate was punitive, aberrational, and lacking consideration of the totality of the circumstances or the seriousness of Unicatch's conduct,'' but deferred further consideration of Unicatch's arguments that the petition rate was unduly punitive.[10]

In its second remand redetermination issued on February 23, 2021, Commerce provided additional analysis concerning the corroboration of the margin assigned to Unicatch as AFA. Commerce also recalculated the rate assigned to the non-examined companies using a simple average of the mandatory respondents' rates.[11]

In *Pro-Team III,* the non-examined companies challenged Commerce's decision to use a simple average of the mandatory respondents' AFA and *de minimis* rates to calculate the rate for non-examined companies. The CIT remanded Commerce's use of a simple average to calculate the rate for non-examined companies.[12] The CIT found that substantial evidence did not support Commerce's departure from the expected method [13] (*i.e.,* using a weighted average to calculate the non-examined companies' rate) because Commerce had not explained why the U.S. Customs and Border Protection (CBP) import volume data it had relied on for selecting mandatory respondents was not reliable for the purpose of calculating a dumping rate using the expected method.[14]

In its third remand redetermination issued on October 13, 2021, Commerce continued to assign rates based on total AFA to two selected respondents (Bonuts and Unicatch), calculated a zero percent margin for a third selected respondent (PT/Pro-Team), and calculated the weighted-average of the rates of these three mandatory respondents to apply to the non-examined companies.[15] This use of the expected method resulted in an AD rate of 35.30 percent for the non-examined companies.[16]

In *Pro-Team IV,* the Court explained that the statute, SAA, and case law supported the legal framework in which the mandatory respondents are assumed representative of the non- examined companies and also explained that Commerce does not bear a burden of data collection to determine non-examined companies' potential dumping margins.[17] The CIT agreed with Commerce's finding that substantial evidence did not support a finding that the mandatory respondents' rates were not representative because the history of the rates showed fluctuations from administrative review to administrative review. Moreover, the CIT held that Commerce's determination to include in the calculation of the rate applicable to non-selected respondents Bonuts' AFA rate was lawful because absent Bonuts' cooperation, Commerce could not verify Bonuts' claim that it was not representative.[18]

On July 15, 2022, the Court sustained Commerce's *Third Redetermination,* and entered a final judgment.[19]

Timken Notice

In its decision in *Timken,*[20] as clarified by *Diamond Sawblades,*[21] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The Court's July 15, 2022, judgment sustaining the *Third Redetermination* constitutes a final decision of the Court that is not in harmony with Commerce's *Final Results.* This notice is published in fulfillment of the publication requirement of *Timken.*

Amended Final Results

Because there is now a final court decision, Commerce is amending the *Final Results* with respect to PT/Pro-Team and the non-examined companies for the period May 20, 2015, through June 30, 2016. The revised rates for PT/Pro-Team and the non-examined companies are as follows:

Producer/exporter	Weighted average dumping margin (percent)
PT Enterprise, Inc./Pro-Team	
Coil Nail Enterprise, Inc	0.00
Non-examined companies [22]	35.30

Cash Deposit Requirements

Because PT/Pro-Team and the non-examined companies have superseding cash deposit rates, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to CBP. This notice will not affect the current cash deposit rates.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by CIT order from liquidating entries that: were imported by PrimeSource Building Products, Inc.; produced and exported by Pro-Team Coil Nail Enterprise, Inc. and/or PT Enterprise Inc.; produced and exported by Hor Liang Industrial Corp. or Romp Coil Nails Industries Inc.; or produced and exported by Unicatch Industrial Co., Ltd., and were entered, or withdrawn from warehouse, for consumption during the period May 20, 2015 through June 30, 2016. Liquidation of these entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision,

[9] *Id.,* 483 F. Supp. 3d at 1245, 1251

[10] *Id.,* 483 F. Supp. 3d at 1251.

[11] *See Final Results of Redetermination Pursuant to Court Remand, Pro-Team Coil Nail Enter.* v. *United States,* Consol. Court No. 18–00027, Slip Op. 20–163 (CIT November 16, 2020), dated February 23, 2021 (*Second Redetermination*), at 12. Upon review of the calculation of the non-examined companies' rate, we found that Commerce erred in the *First Redetermination* by inadvertently omitting Bonuts' rate from the calculation.

[12] *See Pro-Team Coil Nail Enter.* v. *United States,* 532 F. Supp. 3d 1281, 1294 (CIT 2021) (*Pro-Team III*).

[13] The Statement of Administrative Action accompanying the Uruguay Round Agreements Act (URAA), which Congress has approved as an authoritative interpretation of the statute, *Id.* § 3512(d), provides an ''expected method'' to determine the all-others rate in these situations. *See* Statement of Administrative Action Accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–316, Vol. 1 (1994) (SAA), at 873. When the dumping margins for all individually investigated exporters and producers are determined entirely on the basis of facts available or are zero or *de minimis,* ''{t}he expected method in such cases will be to weight-average the zero and *de minimis* margins and margins determined pursuant to the facts available, provided that volume data is available.'' *Id.* The SAA further provides that ''if this method is not feasible, or if it results in an average that would not be reasonably reflective of potential dumping margins for non-investigated exporters or producers, Commerce may use other reasonable methods.'' *Id.*

[14] *See Pro-Team III,* 532 F. Supp. 3d at 1293–94.

[15] *See Final Results of Redetermination Pursuant to Court Remand, Pro-Team Coil Nail Enter.* v. *United States,* Consol. Court No. 18–00027, Slip Op. 21–93 (CIT July 20, 2021), dated October 13, 2021 (*Third Redetermination*).

[16] *Id.* at 17.

[17] *See Pro-Team Coil Nail Enter.* v. *United States,* Consol. Court No. 18–00027, Slip Op. 22–84 (CIT July 15, 2022) (*Pro-Team IV*).

[18] *Id.* at 18.

[19] *Id.*

[20] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[21] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[22] The non-examined companies are Hor Liang Industrial Corp. and Romp Coil Nails Industries Inc.

Commerce intends to instruct CBP to assess ADs on unliquidated entries of subject merchandise imported by PrimeSource Building Products, Inc.; produced and exported by Pro-Team Coil Nail Enterprise, Inc. and/or PT Enterprise Inc.; produced and exported by Hor Liang Industrial Corp. or Romp Coil Nails Industries Inc.; or produced and exported by Unicatch Industrial Co., Ltd., in accordance with 19 CFR 351.212(b). We will instruct CBP to assess ADs on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate is not zero or *de minimis.* Where an importer-specific *ad valorem* assessment rate is zero or *de minimis,*[23] we will instruct CBP to liquidate the appropriate entries without regard to ADs.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516(A)(c) and (e) and 777(i)(1) of the Act.

Dated: July 25, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–16309 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Gas Flow Meter Calibrations

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice of workshop; request for comments.

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, is examining the economic impact and continued need for gas flow calibration services as provided to U.S. industry by the Fluid Metrology Group on NIST's campus in Gaithersburg, Maryland. NIST is also interested in whether there is a need for gas flow meter calibration services not presently offered by NIST. NIST publishes this notice to announce a workshop that will guide NIST planning for the future of its gas flow calibration capabilities, and to request comments on government and industry interest in and needs for (1) gas flow calibrations and whether the present services are meeting those needs, (2) new gas flow calibrations and standards not presently available from NIST, and (3) calibrations and standards for multiphase flows. This is part of the effort to systematically review NIST's Measurement Services to assess gaps and ensure alignment with stakeholders' needs as discussed in the Government Accounting Office report GAO–18–445.

DATES: NIST will accept written responses to this request for information until 11:59 p.m. Eastern Time on September 16, 2022. Submissions received after that date may not be considered. All submissions, including attachments and other supporting materials, may become part of the public record and may be subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

A public workshop will be held on Wednesday, September 7, 2022, from 1:00 p.m. to 4:00 p.m. Eastern Time, virtually by web conferencing. Interested parties must register to participate in the public workshop by 5:00 p.m. Eastern Time on Tuesday, September 6, 2022, and may register by sending an email to *john.wright@nist.gov* prior to 5:00 p.m. Eastern Time on Tuesday, September 6, 2022.

ADDRESSES: Comments should be submitted to Dr. John Wright, Sensor Science Division, Physical Measurement Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8361, Gaithersburg, Maryland 20899, or by electronic mail to *john.wright@nist.gov.* Individuals or groups interested in touring the gas flow standards in person are welcome and can schedule tours by writing to the email address, *john.wright@nist.gov,* before or after the workshops.

FOR FURTHER INFORMATION CONTACT: Mail: Chief, Sensor Science Division, Gas Flow Calibrations, 100 Bureau Drive, Mail Stop 8440, Gaithersburg, Maryland 20899. Email: John Wright at *john.wright@nist.gov.* Phone number: 301 975–5937.

SUPPLEMENTARY INFORMATION: NIST's gas flow standards use the pressure, volume, temperature, and time (PVTt) method and working standard flow meters to conduct research and perform customer calibrations at flows ranging from 0.1 cm^3/min to 4 x 10^4 m^3/min with uncertainties as low as 0.025%. The smaller flows in this range are used by the semiconductor, pharmaceutical, and aerospace manufacturing sectors. The largest flows in the range are performed using high pressure natural gas to support reliable trade of this fuel. More information on NIST's gas flow standards and print publications about them can be found at *https://www.nist.gov/laboratories/tools-instruments/gas-flow-standards.*

NIST is seeking to better understand the impact of its gas flow calibrations on the U.S. economy, manufacturing infrastructure, and technological base, and whether the magnitude of this impact necessitates that NIST should: expand or reduce the calibrations offered; expand the variety of gases used in calibrations beyond nitrogen, noble gases, and natural gas to include semiconductor gases and other hazardous and corrosive gases; and/or improve the uncertainties of the present calibrations.

To measure the impact of NIST gas flow calibration services on the U.S. economy and U.S. manufacturing, NIST welcomes information about the ''leverage'' of NIST calibrations (*i.e.,* cases where a few instruments calibrated by NIST are subsequently used by a commercial laboratory or a flow meter manufacturer to provide traceability and accuracy for a large number of instruments) and ''impact'' of NIST calibrations (*i.e.,* cases where a single calibration has a major impact on a specific commercial, technology, or government application or project).

The following list of topics covers the major areas about which NIST is seeking comments. The listed areas are not intended to limit the topics that may be addressed by respondents so long as they address a topic that would be useful in NIST's planning relative to our offerings of gas flow calibrations. When addressing the topics below, respondents may describe the practices of their organization or organizations with which they are familiar. Providing such information is optional and will not affect NIST's full consideration of the comment.

Topics of Interest

1. Which NIST gas flow calibrations you have purchased, if any, including:

a. If you have purchased calibrations from NIST, whether you purchased from NIST due to convenience, accuracy, cost, customer service, regulatory requirement, or some other reason;

b. If NIST was to terminate the calibration service(s) you presently use, whether you have another source lined

[23] *See* 19 CFR 351.106(c)(2).

up that would meet your requirements; and

c. Whether it would pose a problem to your organization if the calibration service was not available at NIST.

2. How NIST calibration results are applied in your organization, including numerical examples of ''leverage'' to assess the economic impact of NIST flow calibration services. For example: ''Three working standard flow meters periodically calibrated by NIST are the source of calibration traceability for 2,000 flow meters manufactured at our facilities,'' or ''Proficiency testing allows ISO 17025 accreditation of our calibration capabilities that are applied to $1M worth of products annually.''

3. Whether flow calibrations in your organization are traceable to NIST, including:

a. Whether you refer to NIST flow publications or research to support your gas flow measurements; and

b. If not directly traceable to NIST, whether you know how your flow measurements compare to NIST flow standards (for example by comparison against a flow meter traceable to a NIST calibration).

4. Feedback on the cost, availability, turn-around time, business systems, and customer service provided by NIST gas flow calibration services.

5. Whether you purchase gas flow calibrations from another National Metrology Institute (NMI) or from another calibration laboratory, and your organization's experience with this approach.

6. Your opinions about the range, uncertainty, quality and cost of the NIST gas flow calibration services, and whether there are specific, new flow calibration capabilities that NIST should consider offering to better serve your needs. Possibilities include calibrations involving toxic semiconductor gases, multiphase flows, gas mixtures, smaller or larger flows, and wider temperature or pressure ranges. Details about flow ranges and uncertainties of interest, expected frequency of use of the service, and maximum price that you might be willing to pay for the service are also useful.

7. Whether you manufacture and sell gas flow meters or sell calibrations of such meters; if so, whether your meter flow values are traceable to NIST; and, if not NIST, whether you use a secondary laboratory, another NMI, or have your own primary standard(s).

8. Whether there are flow measurement research topics that are not presently being studied that you would like NIST to research, and the potential impact of such research on your organization.

Authority: 15 U.S.C. 272(b) & (c).

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2022–16339 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC209]

Endangered Species; File No. 26268

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Kate Mansfield, Ph.D., University of Central Florida, Biology, 4000 Central Florida Blvd., Bldg. 20, Room 301, Orlando, FL 32816–2368, has applied in due form for a permit to take green (*Chelonia mydas*), hawksbill (*Eretmochelys imbricata*), Kemp's ridley (*Lepidochelys kempii*), leatherback (*Dermochelys coriacea*), and loggerhead (*Caretta caretta*) sea turtles for purposes of scientific research.

DATES: Written, telefaxed, or email comments must be received on or before August 29, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 26268 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26268 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Erin Markin, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to continue three long-term projects on juvenile, subadult, and adult sea turtle populations in the central Indian River Lagoon (Project 1); Trident Turning Basin, Cape Canaveral Space Force Station (Project 2); and Gulf of Mexico waters offshore Louisiana to western Florida (Project 3). Researchers would assess sea turtle population structure, abundance, distribution, habitat, sex ratios, physiology, genetics, epidemiology, and foraging ecology. For Project 1, up to 150 green, two hawksbill, three Kemp's ridley, one leatherback, and 100 loggerhead sea turtles would be captured by tangle or dip net, marked, photographed, measured, weighed, have cloacal temperature measured, and biologically sampled (blood; skin, tumor, and scute biopsy; gastric lavage; voided feces; and/or cloacal, oral, skin and ocular swabs) prior to release. A subset of loggerhead and green sea turtles may receive two transmitter types (satellite, acoustic, or radio) at a time. For Project 2, up to 135 green, one hawksbill, one Kemp's ridley, one leatherback, and 10 loggerhead sea turtles would be captured by tangle or dip net, marked, photographed, measured, weighed, have cloacal temperature measured, and biologically sampled (blood; skin, tumor, and scute biopsy; gastric lavage; voided feces; and/or cloacal, oral, skin and ocular swabs) prior to release. A subset of green sea turtles may receive two transmitter types (satellite, acoustic, or radio) at a time. For Project 3, up to 25 green, five hawksbill, 25 Kemp's ridley, and five loggerhead sea turtles would be captured by dip net, marked, photographed, measured, weighed, have cloacal temperature measured, biologically sampled (blood; skin, tumor, and scute biopsy; gastric lavage; voided feces; and cloacal, oral, skin and ocular swabs), and outfitted with up to two transmitters types (satellite, acoustic, or radio) at a time prior to release. The permit would be valid for 10 years.

Dated: July 26, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–16294 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID: 0648–XC064]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; new five-year affirmative finding for Peru.

SUMMARY: The NMFS Assistant Administrator (Assistant Administrator) has issued a new 5-year affirmative finding for the Government of Peru under the Marine Mammal Protection Act (MMPA). This affirmative finding will allow the importation into the United States of yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP), in compliance with the Agreement on the International Dolphin Conservation Program (AIDCP), by purse seine vessels operating under Peru's jurisdiction or exported from Peru. NMFS bases the affirmative finding determination on reviews of documentary evidence submitted by the Government of Peru and of information obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: This new affirmative finding is effective for the five-year period of April 1, 2022, through March 31, 2027.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, NMFS, by mail: 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, email: *justin.greenman@noaa.gov,* or phone: (562) 980–3264.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP from a nation with jurisdiction over purse seine vessels with carrying capacity greater than 400 short tons that harvest tuna in the ETP only if the nation has an ''affirmative finding'' issued by the NMFS Assistant Administrator. *See* Section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B); *see also* 50 CFR 216.24(f)(6)(i). If requested by the government of such a nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the AIDCP and its obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS must determine whether the harvesting nation continues to meet the requirements of their 5-year affirmative finding. NMFS does this by reviewing the documentary evidence from the last year. A nation may provide information related to compliance with AIDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the AIDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f)(8), the Assistant Administrator considered documentary evidence submitted by the Government of Peru and obtained from the IATTC and has determined that Peru has met the MMPA's requirements to receive a new five-year affirmative finding.

After consultation with the Department of State, the Assistant Administrator issued a new 5-year affirmative finding to Peru, allowing the importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by purse seine vessels operating under Peru's jurisdiction or exported from Peru. Issuance of a new five-year affirmative finding for Peru does not affect implementation of an intermediary nation embargo under 50 CFR 216.24(f)(9), which applies to exports from a nation that exports to the United States yellowfin tuna or yellowfin tuna products that was subject to a ban on importation into the United States under section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B).

This new affirmative finding for Peru is for the five-year period of April 1, 2022, through March 31, 2027, subject to subsequent annual reviews by NMFS.

Dated: July 26, 2022.

Janet Coit,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–16312 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC063]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewals for Colombia, Ecuador, El Salvador, Guatemala, Mexico, and Spain.

SUMMARY: The NMFS Assistant Administrator (Assistant Administrator) has completed an affirmative finding annual renewal for the Governments of Colombia, Ecuador, El Salvador, Guatemala, Mexico, and Spain (referred to hereafter as ''The Nations'') under the Marine Mammal Protection Act (MMPA). These affirmative findings will continue to allow the importation into the United States of yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) for 1 year, in compliance with the Agreement on the International Dolphin Conservation Program (AIDCP), by purse seine vessels operating under The Nations' jurisdiction or exported from The Nations. NMFS bases the affirmative finding annual renewals on reviews of documentary evidence submitted by the Governments of The Nations and of information obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: These affirmative finding annual renewals are effective for the one-year period of April 1, 2022, through March 31, 2023.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, NMFS, by mail: 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, email: *justin.greenman@noaa.gov,* or phone: (562) 980–3264.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP from a nation with jurisdiction over purse seine vessels with carrying capacity greater than 400

short tons that harvest tuna in the ETP only if the nation has an ''affirmative finding'' issued by the NMFS Assistant Administrator. *See* Section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B); *see also* 50 CFR 216.24(f)(6)(i). If requested by the government of such a nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the AIDCP and its obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS must determine whether the harvesting nation continues to meet the requirements of their 5-year affirmative finding. NMFS does this by reviewing the documentary evidence from the last year. A nation may provide information related to compliance with AIDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the AIDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f)(8), for this annual renewal, the Assistant Administrator considered documentary evidence submitted by the Governments of The Nations and obtained from the IATTC and has determined that The Nations have met the MMPA's requirements to receive affirmative finding annual renewals.

After consultation with the Department of State, the Assistant Administrator issued affirmative finding annual renewals to The Nations, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by purse seine vessels operating under The Nations' jurisdiction or exported from The Nations. Issuance of affirmative finding annual renewals for The Nations does not affect implementation of an intermediary nation embargo under 50 CFR 216.24(f)(9), which applies to exports from a nation that exports to the United States yellowfin tuna or yellowfin tuna products that was subject to a ban on importation into the United States under section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B).

These affirmative finding annual renewals for The Nations are for the 1-year period of April 1, 2022, through March 31, 2023. The Nations' individual 5-year affirmative findings, which have varying start and end dates, remain valid. Ecuador, Guatemala, Mexico, and Spain's 5-year affirmative findings will remain valid through March 31, 2025. Colombia's 5-year affirmative finding will remain valid through March 31, 2024, and El Salvador's 5-year affirmative finding will remain valid through March 31, 2023, subject to subsequent annual reviews by NMFS.

Dated: July 26, 2022.

Janet Coit,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–16311 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Public Meeting of the Science Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for the meeting of the Science Advisory Board (SAB). The members will discuss issues outlined in the section on Matters to be Considered.

DATES: The meeting is scheduled for Tuesday, August 30, 2022, 9:30 a.m.–5:00 p.m. Eastern Daylight Time (EDT) and Wednesday, August 31, 2022, 9:00 a.m.–12:30 p.m. Eastern Daylight Time (EDT). The time and the agenda topics described below are subject to change. For the latest agenda, please refer to the SAB website: *https://sab.noaa.gov/index.php/current-meetings/.*

ADDRESSES: The August 30–31, 2022 meeting will be held at the Double Tree by Hilton Silver Spring Washington, DC North located at 8777 Georgia Ave., Silver Spring, MD 20910. The link for the webinar registration for the August 30–31, 2022 meeting may be found here: *https://sab.noaa.gov/index.php/current-meetings/.*

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Phone Number: 202–936–5847; Email: *Cynthia.Decker@noaa.gov;* or visit the SAB website at *https://sab.noaa.gov/index.php/current-meetings/.*

SUPPLEMENTARY INFORMATION: The NOAA Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Status: The August 30–31, 2022 meeting will be open to public participation with a 15-minute public comment period at 4:45 p.m. Eastern Daylight Time (EDT) on Tuesday, August 30, 2022. The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three minutes. Written comments for the August 30–31, 2022 meeting should be received in the SAB Executive Director's Office by August 18, 2022 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after this date will be distributed to the SAB, but may not be reviewed prior to the meeting date.

Special Accommodations: This meeting is physically accessible to people with disabilities. Requests for special accommodations may be directed to the Executive Director no later than 12 p.m. on August 18, 2022.

Matters to be Considered: The meeting on August 30–31, 2022 will include the (1) NOAA Update; (2) NOAA Science Update; (3) Review of the Cooperative Institute for Modelling the Earth System (CIMES); (4) NOAA Response to SAB Climate Working Group Report: Advancing Earth System Prediction; (5) Tsunami Science & Technology Advisory Panel Strategic Plan; (6) NOAA Response to SAB Climate Working Group Review of the Climate and Fisheries Initiative Implementation Approach; (7) Updates

from SAB 2022 Work Plan Topics; (8) Environmental Information Services Working Group Report Review of the NOAA Subseasonal to Seasonal (S2S) Report to Congress; (9) NOAA Response to SAB Climate Working Group Review of the Coastal Inundation at Climate Timescales White Paper. Meeting materials, including work products, will be made available on the SAB website: *https://sab.noaa.gov/index.php/current-meetings/.*

Dave Holst,

Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–16269 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC213]

Marine Mammals; File No. 26170

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Keith Ellenbogen, Blue Reef, 189 Schermerhorn Street, 8E; Brooklyn, NY 11201, in due form for a permit to conduct commercial and educational photography on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before August 29, 2022.

ADDRESSES: These documents are available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26170 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Ph.D., or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to observe, film, and photograph cetaceans and seals within the U.S. northeast Atlantic waters of the U.S., from the Gulf of Maine (including Cape Cod Bay and Stellwagen Bank National Marine Sanctuary) through the New York Bight (Montauk, NY to Cape May, NJ), including the Hudson Canyon. Up to 405 humpback (*Megaptera novaeangliae;* West Indies Distinct Population Segment) and long-finned pilot (*Globicephala melaena*) whales; harbor porpoise (*Phocoena phocoena*); and Atlantic white-sided (*Lagenorhyncus acutus*), bottlenose (*Tursiops truncatus*), long-beaked common (*Delphinus capensis*), Risso's (*Grampus griseus*), short-beaked common (*Delphinus delphis*), and striped (*Stenella coeruleoalba*) dolphins; and up to 675 harbor (*Phoca vitulina*) and gray (*Halichoerus grypus*) seals may be harassed annually from close approaches by marine vessels, experienced swimmers/divers, and during ground surveys for photography and filming purposes. The permit is requested for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: July 26, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–16277 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0058]

Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The duty of candor and good faith in dealing with the United States Patent and Trademark Office (USPTO) includes the duty to disclose to the USPTO information material to the patentability of a claimed invention. Each party submitting a paper to the USPTO has an additional duty to perform an inquiry that is reasonable under the circumstances, including reviewing documents to identify information that is material to the patentability of a claimed invention. The USPTO relies on each individual who is subject to these duties to abide by them. The duties are imposed to assist patent examiners and administrative patent judges in evaluating patentability effectively and efficiently. The duties promote robust and reliable patents, and drive competition and economic growth. In the pharmaceutical space, the duties promote robust and reliable patents that incentivize and protect innovation that brings life-saving drugs to the American people while not unnecessarily delaying more affordable generic drugs. This notice is intended to clarify the duties, including as to materials or statements material to patentability or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other governmental agencies.

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at 571–272–0909.

SUPPLEMENTARY INFORMATION:

I. *Background:* On July 9, 2021, President Biden issued an *Executive Order on Promoting Competition in the American Economy,* 86 FR 36987 (2021). President Biden expressed concern that ''too often, patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.'' The President called for action ''to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.''

On September 9, 2021, Senator Patrick Leahy and Senator Thom Tillis sent a letter to Mr. Andrew Hirshfeld, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, requesting that the Office ''take steps to reduce patent applicants'

making inappropriate conflicting statements in submissions to the [USPTO] and other federal agencies.'' The letter provided a specific example in which ''inconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the [USPTO] to secure a patent on the product.'' The letter noted that such inconsistent statements ''should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions.''

This notice is part of the USPTO's efforts to put into effect the Administration's goals and address the Senators' concerns. It is also part of the USPTO's ongoing mission to issue robust and reliable patents and to make sure our intellectual property ecosystem works to bring more innovation to impact—in every technological space including the critical pharmaceutical space. This notice clarifies the ''duty of disclosure'' and ''duty of reasonable inquiry'' owed to the USPTO and American public. This notice specifically addresses these duties as they relate to information and statements material to patentability including, but not limited to, those received from or submitted to the FDA and other governmental agencies.

II. *Who Has a Duty to Disclose Material Information:* The duty to disclose applies to matters pending before the USPTO and extends broadly to ''[e]ach individual associated with the filing and prosecution of a patent application'' and ''[e]ach individual associated with the patent owner in a reexamination proceeding.'' 37 CFR 1.56(a) and 1.555(a). For patent applications, including reissue applications, these individuals include each inventor named in the application, each attorney or agent who prepares or prosecutes the application, and ''[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.'' 37 CFR 1.56(c); *see* 37 CFR 1.171. For reexamination proceedings, these individuals include ''the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding.'' 37 CFR 1.555(a).

The duty to disclose also extends to parties and individuals involved in a proceeding before the Patent Trial and Appeal Board (PTAB). According to 37 CFR 42.11(a), ''Parties and individuals involved in the proceeding have a duty of candor and good faith to the Office during the course of a proceeding.'' Not only does the duty apply to each individual associated with a patent application (including a reissue application) or reexamination proceeding that is on appeal to the PTAB, but the duty to disclose also extends to patent owners presenting substitute claims in an inter partes review or post grant review proceeding. ''Under 37 CFR 42.11, all parties have a duty of candor, which includes a patent owner's duty to disclose to the Board information of which the patent owner is aware that is material to the patentability of substitute claims, if such information is not already of record in the case.'' *Lectrosonics, Inc.* v. *Zaxcom, Inc.,* IPR2018–001129, 001130, Paper 15 at 9–10 (PTAB Feb. 25, 2019) (precedential).

III. *What Material Information Must Be Disclosed:* ''[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.'' 37 CFR 1.56(b). The USPTO holds those individuals subject to this duty to the highest standards. In close cases where the materiality or consistency of the information is in question, the applicant should consider submitting this information to the USPTO. *See* Manual of Patent Examining Procedure (9th ed. Rev. 10.2019) (MPEP) § 2004, item 10.

Specifically, the duty of candor and good faith, and by extension the duty to disclose, applies to positions taken by applicants or parties involving the claimed subject matter. For instance, in PTAB proceedings, parties should not take a position about the patentability of challenged claims that is inconsistent with positions taken in submissions to other Government agencies regarding the same subject matter. *See, e.g.,* Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, Final Rule, 77 FR 48612, 48630 (Aug. 14, 2012) (''The scope of the duty [of candor and good faith] is comparable to the obligations toward the tribunal imposed by Rule 11 of the Federal Rules of Civil Procedure.'').

If a party to a USPTO proceeding discovers that an earlier position taken in a submission to the USPTO or another Government agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record. *See, e.g., In re Tendler,* Proceeding No. D2013–17 (USPTO Jan. 1, 2014) (suspending a practitioner for four years for failure to correct the written record after learning of inaccuracies in a declaration the practitioner had filed). In the context of prosecution, an applicant must disclose to the USPTO any information that refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability. *See* 37 CFR 1.56(b)(2). In the context of PTAB proceedings, if the party is or becomes aware of incorrect or inconsistent positions, the party must make the PTAB panel aware of the incorrect or inconsistent positions and must submit the inconsistent information. Patent owners may bring information, including prior art and incorrect or inconsistent positions, to the attention of the USPTO through supplemental examination, *ex parte* reexamination, reissue applications, or submissions under 37 CFR 1.501. During prosecution, third parties may have an opportunity to disclose information to the USPTO through third party submissions under 37 CFR 1.290 and protests under 37 CFR 1.291. After issuance, third parties may disclose information directed to issued patents to the USPTO via submissions under 37 CFR 1.501, in *ex parte* reexamination, or in PTAB trial proceedings. A finding of ''fraud,'' ''inequitable conduct,'' or violation of duty of disclosure through bad faith or intentional misconduct with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. MPEP § 2016.

Patent examiners also have the ability to require submission of information that may be reasonably necessary to properly examine or treat a matter in a pending or abandoned application. 37 CFR 1.105(a)(1). The information that must be submitted to comply with a requirement for information under 37 CFR 1.105 may not be material to patentability in itself under 37 CFR 1.56, but it is necessary to obtain a complete record from which a determination of patentability may be made. MPEP § 704.12(a). Therefore, when an examiner has a reasonable

basis to conclude that an individual identified under 37 CFR 1.56(c) or any assignee has information that would aid in the examination of the application or treatment of some matter, the examiner may require submission of information that is not necessarily material to patentability. This requirement could include statements made or information submitted to other Government agencies such as the FDA. For example, when examining a claim directed to a process of manufacturing a particular drug product that was effectively filed more than one year after FDA approval of the drug product, an examiner may appropriately require an applicant to submit to the USPTO information submitted to the FDA (*e.g.,* in a New Drug Application or Biologics License Application) on how the drug product was manufactured.

IV. *What Is the Duty of Reasonable Inquiry:* ''The presentation to the Office (whether by signing, filing, submitting, or later advocating) of any paper by a party, whether a practitioner or non-practitioner, constitutes a certification under § 11.18(b).'' 37 CFR 1.4(d)(4)(i). Section 11.18(b) includes 11.18(b)(2), which calls for a duty of reasonable inquiry to ensure that the paper is not being presented for any improper purpose, the legal contentions are warranted by law, the allegations and other factual contentions have evidentiary support, and the denials of factual contentions are warranted on the evidence.[1]

Accordingly, each party presenting a paper to the USPTO, whether a practitioner or non-practitioner, has a duty to perform an inquiry that is reasonable under the circumstances. This reasonable inquiry may comprise reviewing documents that are submitted to or received from other Government agencies, including the FDA. If any reviewed document is material to the patentability of a pending matter before the Office, such as a patent application (including a reissue application), a reexamination proceeding, or an issue pending before the PTAB, the party has a duty to submit the information to the USPTO. 37 CFR 1.56, 1.555, 42.11(a); *see* 37 CFR 42.11(c), 11.18(b)(2). A duty of reasonable inquiry may exist based on circumstances known to the party presenting the paper to the USPTO. Failing to inquire when the circumstances warrant it could result in sanctions or other action under 37 CFR 11.18(c), which may include: (1) striking the offending paper; (2) referring a practitioner's conduct to the Director of Enrollment and Discipline for appropriate action; (3) precluding a party or practitioner from submitting a paper, or presenting or contesting an issue; (4) affecting the weight given to the offending paper; or (5) terminating the proceedings in the Office. *See, e.g., In re Hao,* Proceeding No. D2021–14 (USPTO Apr. 27, 2022) (involving disciplinary sanctions predicated on non-compliance with 37 CFR 11.18).

V. *When the Duties of Disclosure and Reasonable Inquiry Arise in Dealings With Other Government Agencies:* Each individual with a duty to disclose, or party with a duty of reasonable inquiry, should ensure that the statements made to the USPTO and other Government agencies, or any statements made on their behalf to other Government agencies regarding the claimed subject matter, are consistent. *See Belcher Pharms., LLC* v. *Hospira, Inc.,* 11 F.4th 1345 (Fed. Cir. 2021) (affirming a district court's determination of inequitable conduct because the patent owner's Chief Science Officer failed to provide to the USPTO submissions he made to the FDA about the prior art that were inconsistent with positions taken before the USPTO during the prosecution of a pending patent application). Furthermore, providing material information to other Government agencies, including the FDA, while simultaneously withholding the same information from the USPTO undermines both the intent and spirit of the duty of disclosure and violates those duties. For example, in *Bruno Independent Living Aids, Inc.* v. *Acorn Mobility Services, Ltd.,* 394 F.3d 1348, 1354 (Fed. Cir. 2005), the U.S. Court of Appeals for the Federal Circuit inferred intent to deceive and found inequitable conduct occurred when an official involved in both the FDA and the USPTO submissions chose to disclose material prior art to the FDA but not to the USPTO.

Activities or documents associated with market testing, marketing, or commercialization by the patent applicant can also be material to patentability, and therefore, when material, should be disclosed to the USPTO. *See GS Cleantech Corp.* v. *Adkins Energy LLC,* 951 F.3d 1310, 1330–1332 (Fed. Cir. 2020) (finding that a district court did not abuse its discretion in reaching its inequitable conduct determination where the district court concluded that the inventors and their lawyers made a deliberate decision to withhold material information from the USPTO regarding an offer for sale and reduction to practice of the claimed invention that would have implicated an on-sale bar to the granting of a patent; the lawyers filed with the USPTO a declaration containing a false statement about the timing of an offer for sale despite having in their possession materials that would call into question the veracity of the statement; and the inventors and lawyers subsequently failed to correct the false declaration). By following the guidance in this notice, it is expected that patent applicants can obtain more reliable patent protection and avoid the findings of inequitable conduct and sanctions noted above.

Similarly, each individual with a duty to disclose, or party with a duty of reasonable inquiry, should review documents it receives from other Government agencies to determine whether the information should be submitted to the USPTO. For example, when a company seeks FDA approval to market a generic drug before the expiration of patents related to the drug, the generic drug application (*e.g.,* an Abbreviated New Drug Application (ANDA)) must contain a ''paragraph IV certification'' that the patents submitted to the FDA by the brand-name drug's sponsor, listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), and related to the drug are invalid, are unenforceable, or will not be infringed by the generic product. Except in limited circumstances, notice of a paragraph IV certification must also be communicated to the owner of the patent subject to the certification and to the New Drug Application holder. Such a notice includes a detailed statement providing factual and legal bases for the paragraph IV certification. 21 CFR 314.95(c)(7). Consequently, to assist USPTO staff in evaluating patentability effectively and efficiently, the party receiving a paragraph IV certification should review such documents to determine whether they are material to the patentability of any pending matters before the USPTO, such as pending patent applications, reexamination proceedings, or issues in proceedings pending before the PTAB. If the content

[1] ''To the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, (i) The paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or needless increase in the cost of any proceeding before the Office; (ii) The other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; (iii) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and (iv) The denials of factual contentions are warranted on the evidence, or if specifically so identified, are reasonably based on a lack of information or belief.'' 37 CFR 11.18(b)(2).

of the detailed statement, or other information that is part of the ANDA process, is deemed material to patentability in a pending USPTO matter, then such information must be submitted to the USPTO during the pendency of the matter, to meet the duties of candor and good faith and disclosure under 37 CFR 1.56, 1.555, 42.11(a) or (c), or 11.18(b)(2).

Deliberate schemes or established practices to prevent 37 CFR 1.56(c) individuals from obtaining knowledge of material information is not acting in accordance with candor and good faith under 37 CFR 1.56(a). For example, walling off the patent prosecution practitioners from the attorneys seeking FDA approval, as a way to prevent material information from being exchanged between the practitioners and attorneys, is inappropriate. The U.S. Supreme Court has refused to enforce patents where deliberate steps were taken to suppress material information. *See, e.g., Keystone Driller Co.* v. *Gen. Excavator Co.,* 290 U.S. 240 (1933) (patent owner's suit dismissed where the patent owner paid a third party to keep a prior use secret); *Precision Instruments Mfg. Co.* v. *Auto. Maint. Mach. Co.,* 324 U.S. 806 (1945) (suit dismissed where patent owner actively suppressed evidence of perjury to the USPTO).

Though the FDA compiles paragraph IV certifications and publishes a list on its website, submitting this list to the USPTO does not satisfy the duty of disclosure for any material information submitted with the paragraph IV certification. These lists do not include patent numbers, relevant claims, or an explanation of the basis for the certification. Therefore, information and documents submitted with the paragraph IV certification that are material to patentability or to issues in proceedings pending before the USPTO, including the PTAB, must be submitted directly to the USPTO and as described above, the examiner may appropriately require submission of information concerning the certifications in certain situations.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–16299 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* August 28, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024–3243.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 4/29/2022, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) and service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Facility Support Services
Mandatory for: U.S. Navy, DFAS Command Building, Bratenahl, Ohio
Designated Source of Supply: VGS, Inc., Cleveland, OH
Contracting Activity: DEPT OF THE NAVY, NAVAL FAC ENGINEERING CMD MID LANT

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–16278 Filed 7–28–22; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: August 28, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024–3243.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8465–00–262–5237—Lanyard, Pistol, White
8465–00–965–1705—Lanyard, Pistol, Olive Green

Mandatory Source of Supply: Work, Incorporated, Dorchester, MA
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–16279 Filed 7–28–22; 8:45 am]

BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NCCC Service Project Application

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Corporation for National and Community Service, operating as AmeriCorps, has submitted a public information collection request (ICR) entitled NCCC Service Project Application for review and approval in accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by August 29, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Ken Goodson, at 202–489–5766 or by email to *kgoodson@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on May 23, 2022 at Vol. 87, 3218. This comment period ended July, 23, 2022. Zero public comments were received from this Notice.

Title of Collection: NCCC Service Project Application.

OMB Control Number: 3045–0010. Type of Review: Renewal.

Respondents/Affected Public: Current and prospective AmeriCorps NCCC sponsors.

Total Estimated Number of Annual Responses: 1,800.

Total Estimated Number of Annual Burden Hours: 17,100.

Abstract: The AmeriCorps NCCC Service Project Application is completed by organizations interested in sponsoring an AmeriCorps National Civilian Community Corps (NCCC) team. Each year, AmeriCorps NCCC engages teams of members in projects in communities across the United States. Service projects, which typically last from six to eight weeks, address critical needs in natural and other disasters, infrastructure improvement, environmental stewardship and conservation, energy conservation, and urban and rural development. Members construct and rehabilitate low-income housing, respond to natural disasters, clean up streams, help communities develop emergency plans, and address other local needs.

AmeriCorps has made several changes to the application in an effort to streamline it for users. Based on feedback from stakeholders, the application now has additional project objective options users may select, and the radio buttons have been changed to check boxes to allow users to select as many objectives as they would like. The NCCC Service Project Application was also simplified by deleting the ''Organizational Capacity'' and ''Needs'' narrative pages.

AmeriCorps seeks to renew the current information collection.The revisions are intended to simplify the application process for prospective sponsors. The information collection will otherwise be used in the same manner as the existing application. AmeriCorps also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on 10/31/2022.

Dated: July 26, 2022.

Walter Goodson,

Director, AmeriCorps NCCC.

[FR Doc. 2022–16334 Filed 7–28–22; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES:

Day 1—Open to the public Tuesday, September 13, 2022 from 8 a.m. to 12:30 p.m.

Day 2—Open to the public Wednesday, September 14, 2022 from 8 a.m. to 12 p.m.

ADDRESSES: The address of the open meeting is the Association of the United States Army Conference Center, located at 2425 Wilson Boulevard, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: COL Seana Jardin, (571) 232–7415 (voice), *seana.m.jardin.mil@mail.mil* (email). Website: *https://dacowits.defense.gov.*

The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available at the DACOWITS website, *https://dacowits.defense.gov/.* Materials presented in the meeting may also be obtained on the DACOWITS website.

Purpose of the Meeting: The purpose of the meeting is for the DACOWITS to receive briefings and have discussions on topics related to the recruitment, retention, employment, integration, well-being, and treatment of women in the Armed Forces of the United States.

Agenda:

Tuesday, September 13, 2022, from 8 a.m. to 12:30 p.m.—Welcome, Introductions, Announcements, Request for Information Status Update, Briefings, DACOWITS discussion, and a Public Comment Period.

Wednesday, September 14, 2022, from 8 a.m. to 12 p.m.—Welcome, Introductions, Announcements, Briefings, and DACOWITS discussion.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to availability of space, from 8 a.m. to 12:30 p.m. on September 13, 2022 and 8 a.m. to 12 p.m. on September 14, 2022.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Robert Bowling no later than Tuesday, September 6, 2022 so that appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the FACA, interested persons may submit a written statement to the DACOWITS. Individuals submitting a written statement must submit their statement no later than 5 p.m., Tuesday, September 6, 2022 to Mr. Robert Bowling (703) 380–0116 (voice) or to *robert.d.bowling1.mil@mail.mil* (email). Mailing address is 4800 Mark Center Drive, Suite 04J25–01, Alexandria, VA 22350. If members of the public are interested in making an oral statement, a written statement must be submitted. If a statement is not received by Tuesday, September 6, 2022, prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DACOWITS during this quarterly business meeting. After reviewing the written statements, the Chair and the Designated Federal Officer (DFO) will determine if the requesting persons are permitted to make an oral presentation The DFO will review all timely submissions with the DACOWITS Chair and ensure they are provided to the members of the DACOWITS.

Dated: July 25, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–16297 Filed 7–28–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–1061–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (BP 55005 to BP 55484) to be effective 7/23/2022.

Filed Date: 7/25/22.

Accession Number: 20220725–5033.

Comment Date: 5 pm ET 8/8/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 25, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16302 Filed 7–28–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–184–000.

Applicants: TN Solar 1, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of TN Solar 1, LLC.

Filed Date: 7/22/22.

Accession Number: 20220722–5140.

Comment Date: 5 p.m. ET 8/12/22.

Docket Numbers: EG22–185–000.

Applicants: EEC Skyhawk Lessee LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of EEC Skyhawk Lessee LLC.

Filed Date: 7/22/22.

Accession Number: 20220722–5142.

Comment Date: 5 p.m. ET 8/12/22.

Docket Numbers: EG22–186–000.

Applicants: Top Hat Wind Energy LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Top Hat Wind Energy LLC.

Filed Date: 7/25/22.

Accession Number: 20220725–5065.

Comment Date: 5 p.m. ET 8/15/22.

Docket Numbers: EG22–187–000.

Applicants: Top Hat Wind Energy Holdings LLC.

Description: Top Hat Wind Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 7/25/22.

Accession Number: 20220725–5070.

Comment Date: 5 p.m. ET 8/15/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–78–000.

Applicants: Industrial Energy Consumers of America, et al. v. *Midcontinent Independent System Operator, Inc.*

Description: Complaint of Industrial Energy Consumers of America, et al.

Filed Date: 7/22/22.

Accession Number: 20220722–5173.

Comment Date: 5 p.m. ET 8/11/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–1555–002.

Applicants: New Mexico Wind, LLC.

Description: Refund Report: Refund Report Filing Under Docket ER21–1555 to be effective N/A.

Filed Date: 7/25/22.

Accession Number: 20220725–5076.

Comment Date: 5 p.m. ET 8/15/22.

Docket Numbers: ER22–2141–000.

Applicants: Sun Mountain Solar 1, LLC.

Description: Agreement to the Release of Non-Public Information of Sun Mountain Solar 1, LLC.

Filed Date: 7/21/22.

Accession Number: 20220721–5151.

Comment Date: 5 p.m. ET 8/11/22.

Docket Numbers: ER22–2210–001.

Applicants: Public Service Company of Colorado.

Description: Tariff Amendment: 2022–07–22–PSCo-CSU–WACM–666-Amnd to be effective 6/29/2022.

Filed Date: 7/22/22.
Accession Number: 20220722–5137.
Comment Date: 5 p.m. ET 8/12/22.
Docket Numbers: ER22–2283–000; ER22–2284–000.
Applicants: Black Bear Alabama Solar Tenant, LLC, Black Bear Alabama Solar 1, LLC.
Description: Agreement to the Release of Non-Public Information of Black Bear Alabama Solar 1, LLC, et al.
Filed Date: 7/21/22.
Accession Number: 20220721–5150.
Comment Date: 5 p.m. ET 8/11/22.
Docket Numbers: ER22–2470–000.
Applicants: Katmai Energy, LLC.
Description: Notice of Cancellation of Market Based Rate Tariff of Katmai Energy, LLC.
Filed Date: 7/20/22.
Accession Number: 20220720–5206.
Comment Date: 5 p.m. ET 8/10/22.
Docket Numbers: ER22–2471–000.
Applicants: Freeport McMoRan Copper & Gold Energy Services LLC.
Description: Request for Renewed Authorization to Undertake Affiliate Sales of Freeport-McMoRan Copper & Gold Energy Services.
Filed Date: 7/21/22.
Accession Number: 20220721–5152.
Comment Date: 5 p.m. ET 8/11/22.
Docket Numbers: ER22–2472–000.
Applicants: Lockhart Transmission Holdings, LLC.
Description: Petition for Waivers and Blanket Authorization under section 204 of Lockhart Transmission Holdings, LLC.
Filed Date: 7/22/22.
Accession Number: 20220722–5170.
Comment Date: 5 p.m. ET 8/12/22.
Docket Numbers: ER22–2473–000.
Applicants: Florida Power & Light Company.
Description: § 205(d) Rate Filing: FPL Amendment to NITSA and NOA with City of Blountstown to be effective 12/31/9998.
Filed Date: 7/25/22.
Accession Number: 20220725–5069.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2474–000.
Applicants: Top Hat Wind Energy LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 9/24/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5072.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2475–000.
Applicants: Top Hat Wind Energy Holdings LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 9/24/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5073.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2476–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: OATT Modifications—MOD–030 to be effective 10/5/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5074.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2477–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: ISA, SA No. 6542 and CSA, SA No. 6543; Queue No. AC1–033 to be effective 6/23/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5095.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2478–000.
Applicants: Skylar Energy LP.
Description: Tariff Amendment: Notice of Cancellation of Market Based Rate Tariff and Request for Waiver to be effective 7/26/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5097.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2479–000.
Applicants: Skylar Resources LP.
Description: Tariff Amendment: Notice of Cancellation of Market Based Rate Tariff and Request for Waiver to be effective 7/26/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5099.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2480–000.
Applicants: Black Hills Power, Inc.
Description: § 205(d) Rate Filing: Filing of Jurisdictional Agreements to be effective 12/31/9998.
Filed Date: 7/25/22.
Accession Number: 20220725–5129.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2481–000.
Applicants: Seven Cowboy Wind Project, LLC.
Description: Baseline eTariff Filing: Seven Cowboy Wind Project, LLC MBR Tariff to be effective 8/31/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5133.
Comment Date: 5 p.m. ET 8/15/22.
Docket Numbers: ER22–2482–000.
Applicants: 25 Mile Creek Windfarm LLC.
Description: Baseline eTariff Filing: 25 Mile Creek Windfarm LLC MBR Tariff to be effective 7/26/2022.
Filed Date: 7/25/22.
Accession Number: 20220725–5137.
Comment Date: 5 p.m. ET 8/15/22

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 25, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16301 Filed 7–28–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9874–01–OW]

Notice of Availability of the Deepwater Horizon Oil Spill Texas Trustee Implementation Group Final Restoration Plan/Environmental Assessment #2: Restoration of Wetlands, Coastal, and Nearshore Habitats; Nutrient Reduction; Oysters; Sea Turtles; and Birds and Finding of No Significant Impact

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA) and the National Environmental Policy Act (NEPA), the Federal and State natural resource trustee agencies for the Texas Trustee Implementation Group (Texas TIG) prepared the Final Restoration Plan/Environmental Assessment #2: Restoration of Wetlands, Coastal, and Nearshore Habitats; Nutrient Reduction; Oysters; Sea Turtles; and Birds (Final RP/EA #2). The Final RP/EA #2 describes and, in conjunction with the associated Finding of No Significant Impact (FONSI), selects thirteen restoration project alternatives considered by the Texas TIG to restore natural resources and ecological services injured or lost as a result of the *Deepwater Horizon* oil spill. The Texas TIG evaluated these alternatives in accordance with the OPA, including

criteria set forth in the OPA natural resource damage assessment (NRDA) regulations, and evaluated the environmental consequences of the restoration alternatives in accordance with the NEPA. The selected projects are consistent with the restoration alternatives selected in the Deepwater Horizon Oil Spill: Final Programmatic Damage Assessment and Restoration Plan and Final Programmatic Environmental Impact Statement (PDARP/PEIS). The Federal Trustees of the Texas TIG have determined that implementation of the Final RP/EA #2 is not a major Federal action significantly affecting the quality of the human environment within the context of the NEPA. They have concluded a FONSI is appropriate, and, therefore, an Environmental Impact Statement will not be prepared. This notice informs the public of the approval and availability of the Final RP/EA #2 and FONSI.

ADDRESSES: *Obtaining Documents:* You may download the Final RP/EA #2 and FONSI at *https://www.gulfspillrestoration.noaa.gov/restoration-areas/texas.* Alternatively, you may request a compact disc (CD) of the Final RP/EA #2 and FONSI (see **FOR FURTHER INFORMATION CONTACT** section). You may also view the Final RP/EA #2 and FONSI at the following locations:

- Port Arthur Public Library, 4615 9th Avenue, Port Arthur, TX 77642
- Jack K. Williams Library, Texas A&M University at Galveston, 200 Seawolf Parkway Building #3010, Galveston, TX 77554
- Mary and Jeff Bell Library, Texas A&M University—Corpus Christi, 6300 Ocean Drive, Corpus Christi, TX 78412

FOR FURTHER INFORMATION CONTACT:

- Texas—Angela Schrift; *Angela.Schrift@tpwd.texas.gov;* 512–389–8755.
- EPA—Douglas Jacobson; *jacobson.doug@epa.gov;* 214–665–6692.

SUPPLEMENTARY INFORMATION:

Introduction

On April 20, 2010, the mobile offshore drilling unit *Deepwater Horizon,* which was being used to drill a well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252–MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in the release of an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The *Deepwater Horizon* oil spill is the largest offshore oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. The Trustees conducted the natural resource damage assessment for the *Deepwater Horizon* oil spill under the OPA. Under the OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions required to compensate the public for those injuries and losses. The OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time restoration to baseline (*i.e.,* the resource quality and conditions that would exist if the spill had not occurred) is complete.

The *Deepwater Horizon* oil spill Trustees are:

- U.S. Environmental Protection Agency (EPA);
- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- State of Texas Parks and Wildlife Department (TPWD), General Land Office (TGLO), and Commission on Environmental Quality (TCEQ);
- State of Louisiana Coastal Protection and Restoration Authority, Oil Spill Coordinator's Office, Department of Environmental Quality, Department of Wildlife and Fisheries, and Department of Natural Resources;
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama; and
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission.

On April 4, 2016, the Trustees reached and finalized a settlement of their natural resource damage claims with BP in a Consent Decree approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in the Texas Restoration Area are chosen and managed by the Texas TIG. The Texas TIG is composed of the following Trustees: TPWD, TGLO, TCEQ, EPA, DOI, NOAA, and USDA.

Background

A Notice of Availability of the Deepwater Horizon Oil Spill Texas Trustee Implementation Group Draft Restoration Plan/Environmental Assessment #2: Restoration of Wetlands, Coastal, and Nearshore Habitats; Nutrient Reduction; Oysters; Sea Turtles; and Birds (Draft RP/EA #2) was published in the **Federal Register** at 87 FR 10787 on February 25, 2022. The Texas TIG hosted a public webinar on March 9, 2022, and the public comment period for the Draft RP/EA #2 closed on March 28, 2022. In the Draft RP/EA #2, the Texas TIG evaluated eighteen restoration project alternatives in accordance with the OPA and the NEPA. Of these restoration project alternatives, thirteen were identified as preferred, and five were identified as non-preferred. The Draft RP/EA #2 also evaluated a no-action alternative. The Texas TIG considered the public comments received on the Draft RP/EA #2 which informed the Texas TIG's analyses and selection of thirteen restoration projects for implementation in the Final RP/EA #2. A summary of the public comments received and the Trustees' responses to those comments are included in Chapter 7 of the Final RP/EA #2.

Overview of the Final RP/EA

The Final RP/EA #2 is being released in accordance with the OPA, its NRDA implementing regulations, and the NEPA. In the Final RP/EA #2, the Texas TIG selects the following preferred project alternatives for each restoration type:

Wetlands, Coastal, and Nearshore Habitats

- Bird Island Cove Habitat Restoration—Construction;
- Bahia Grande Channel F Hydrologic Restoration;
- Follets Island Habitat Acquisition Phase 2; and
- Galveston Island Habitat Acquisition.

Nutrient Reduction

- Petronila Creek Constructed Wetlands Planning; and
- Petronila Creek Watershed Nutrient Reduction Initiative.

Oysters

- Landscape Scale Oyster Restoration in Galveston Bay.

Sea Turtles

- Upper Texas Coast Sea Turtle Rehabilitation Facility; and
- Reducing Sea Turtle Mortality through Removal of Illegal Fishing Gear.

Birds

- Laguna Vista Rookery Island

Habitat Protection;
- Jones Bay Oystercatcher Habitat Restoration;
- San Antonio Bay Bird Island; and
- Texas Breeding Shorebird and Seabird Stewardship.

The total estimated cost of the selected restoration projects is approximately $39 million. The Texas TIG has examined the injuries assessed by the *Deepwater Horizon* Trustees and evaluated restoration alternatives to address the injuries. In the Final RP/EA #2, the Texas TIG presents to the public the Texas TIG's most recent plan to restore natural resources and ecological services injured or lost as a result of the *Deepwater Horizon* oil spill. Additional restoration planning for the Texas Restoration Area will continue.

Administrative Record

The documents comprising the Administrative Record for the Final RP/EA #2 and FONSI can be viewed electronically at *https://www.doi.gov/deepwaterhorizon/adminrecord* under folder 6.5.7.2.2.

Authority

The authority for this action is the OPA (33 U.S.C. 2701 *et seq.*), its implementing NRDA regulations found at 15 CFR part 990, and the NEPA (42 U.S.C. 4321 *et seq.*).

Benita Best-Wong,

Deputy Assistant Administrator, Office of Water.

[FR Doc. 2022–15846 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–027]

Environmental Impact Statements; Notice of Availability

Responsible agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed July 18, 2022 10 a.m. EST Through July 25, 2022 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20220104, Draft, BR, AZ, White Mountain Apache Tribe Rural Water System, Comment Period Ends: 09/12/2022, Contact: Dominic Graziani 623–773–6216.

EIS No. 20220105, Final, USFS, NM, Santa Fe National Forest Land Management Plan, Review Period Ends: 08/29/2022, Contact: Sarah Browne 505–414–3301.

EIS No. 20220106, Final, USCG, MARAD, TX, SPOT Deepwater Port, Review Period Ends: 09/12/2022, Contact: Matthew Layman 202–372–1421.

EIS No. 20220107, Draft, USACE, FL, Lake Okeechobee System Operating Manual, Comment Period Ends: 09/12/2022, Contact: Jessica M. Menichino 904–858–5101.

EIS No. 20220108, Final, TVA, TN, Clinch River Nuclear Site Advanced Nuclear Reactor Technology Park, Review Period Ends: 08/29/2022, Contact: J. Taylor Johnson 423–751–2732.

Amended Notice

EIS No. 20220060, Draft, BLM, NM, SunZia Southwest Transmission Project, Comment Period Ends: 08/01/2022, Contact: Adrian Garcia 505–954–2199. Revision to FR Notice Published 04/29/2022; Extending the Comment Period from 07/28/2022 to 08/01/2022.

Dated: July 26, 2022.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–16274 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2011–0234; FRL–10101–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Petroleum Refineries (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Petroleum Refineries (EPA ICR Number 1692.13, OMB Control Number 2060–0340), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through July 31, 2021. Public comments were previously requested via the **Federal Register** on May 12, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 29, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2011–0234, online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities at petroleum refineries are required to comply with reporting and record keeping requirements for the

General Provisions (40 CFR part 63, subpart A), as well as the specific requirements at 40 CFR part 63, subpart CC. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Petroleum refineries that are major sources of hazardous air pollutants (HAP).

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

Estimated number of respondents: 142 (total).

Frequency of response: Initially, quarterly, semiannually, and annually.

Total estimated burden: 614,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $98,000,000 (per year), which includes $32,600,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates:

This ICR incorporates the burden from both ICR 1692.10 and ICR 1692.12, which detail the additional burden to petroleum refineries from the December 1, 2015 (80 FR 75178) and November 18, 2018 (83 FR 60696) amendments to the rule, respectively. The 2015 rule amendments added new recordkeeping and reporting requirements for delayed coking unit vents, flares used as control devices, and fenceline monitoring, as well as additional requirements for storage vessels. The 2018 rule amendments revised the recordkeeping requirements for maintenance vents associated with equipment containing less than 72 lbs of VOC. This ICR accounts for the full burden of the current rule and reflects an increase in burden hours and responses.

This ICR, by in large, reflects the on-going burden and costs for existing facilities, with the exception of a small number of facilities with reconstructed units that must meet initial compliance requirements. The burden in this ICR accounts for implementation of the 2015 amendments, which have been in effect for more than three years. The previous ICR reflected those burdens and costs associated with the initial activities for subject facilities, such as purchasing monitoring equipment and establishing recordkeeping systems. As such, the capital/startup costs as calculated in section 6(b)(iii) in this ICR have decreased compared with the costs in the previous ICRs (ICR 1692.10 and ICR 1692.12). In the next three years, the ongoing O&M costs for affected existing facilities at refineries from the 2015 amendments have been adjusted to include the O&M costs for pressure relief valves to address API/APEM comments. In addition, this ICR also adjusts the estimated number of Group 1 storage vessels subject to requirements from 9 to 12 for each facility, per consideration of comments by API/APFM in a letter dated February 14, 2019 and confirmed through Agency analysis.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–16300 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0097; FRL–10091–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Municipal Solid Waste Landfills (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Municipal Solid Waste Landfills (EPA ICR Number 1938.08, OMB Control Number 2060–0505) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through July 31, 2022. Public comments were previously requested via the **Federal Register** on April 13, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 29, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2021–0097, to EPA using *https://www.regulations.gov/* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Municipal Solid Waste Landfills (40 CFR part 63, subpart AAAA) apply to existing and new municipal solid waste (MSW) landfills that have accepted waste since November 8, 1987 or have additional capacity for waste deposition, including those that operate as bioreactors, and the landfill either: (1) is a major source or is collocated with a major source; or (2) is an area source with a design capacity of 2.5 million megagrams (Mg) and 2.5 million cubic meters (m^3), and emits either equal to or greater than 50 tons per year of non-methane organic compounds (NMOC). In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of any period during which the monitoring system is inoperative. These notifications, reports, and records are

essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: 5900–522.

Respondents/affected entities: Municipal solid waste (MSW) landfills.

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

Estimated number of respondents: 1,169 (total).

Frequency of response: Annual, semi-annual.

Total estimated burden: 35,500 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,290,000 (per year), includes $11,100 annualized capital or operation & maintenance costs.

Changes in the estimates: There is a small decrease in burden from the most recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to several considerations. The regulations have been amended in the past three years. The March 26, 2020 amendments revised NESHAP Subpart AAAA, NSPS Subpart XXX and EG Subpart Cf to allow affected sources to demonstrate compliance with landfill gas control, operating, monitoring, recordkeeping, and reporting requirements by following the corresponding requirements in the MSW Landfills NESHAP, harmonizing the control requirements across all of the landfill rules. The 2020 amendments removed the SSM requirements from Subpart AAAA, resulting in a decrease in labor burden. The 2020 amendments added a new semiannual wet landfill monitoring report requirement, resulting in an increase in burden. Since the 2020 amendments also added an annual wet landfill monitoring report requirement to Subparts Cf and XXX, the additional burden to Subpart AAAA sources for this report consists of one additional report per year. The growth rate for this industry is low (two new landfills per year), resulting in a small increase in burden. There are no changes in the capital/startup or operation and maintenance (O&M) costs. The labor burden for re-familiarizing with the regulatory requirements each year was increased from 1 hour to 5 hours, so that the labor burden for this requirement is consistent with that of other NESHAPs. These changes resulted in a small decrease in labor burden (hours), and a small increase in labor costs, resulting in a small increase in costs from the previous ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–16250 Filed 7–28–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 29, 2022.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Elevation Bancshares, Inc., St. Louis, Missouri;* to become a bank holding company by acquiring The First National Bank of Sedan, Sedan, Kansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–16329 Filed 7–28–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 15, 2022.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *The Robert D. Frandsen Revocable Trust U/A dated November 18, 2021, Robert D. Frandsen, as trustee, and the Rennaye M. Frandsen Revocable Trust U/A dated November 18, 2021, Rennaye M. Frandsen, as trustee, all of Rush City, Minnesota;* to become members of the Frandsen Family Control Group, a group acting in concert, to retain voting shares of Frandsen Financial Corporation, Arden Hills, Minnesota, and thereby indirectly retain voting shares of Frandsen Bank & Trust, Lonsdale, Minnesota; Bank of Zumbrota, Zumbrota, Minnesota; and Pine Island Bank, Pine Island, Minnesota (collectively, ''the Banks'').

Additionally, Amy Knox, Palm Desert, California; Alexander Knox, White Bear Lake, Minnesota; Luca Bonvicini, White Bear Lake, Minnesota; Elena Bonvicini, Laguna Beach, California; Brittany Frandsen, Minneapolis, Minnesota; Johnay Frandsen, Minneapolis,

Minnesota; and Frandsen Family Foundation, North Branch, Minnesota, Dennis Frandsen, as trustee, Rush City, Minnesota, to become members of the Frandsen Family Control Group, a group acting in concert, to acquire voting shares of Frandsen Financial Corporation, and thereby indirectly acquire voting shares of the Banks.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–16328 Filed 7–28–22; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0283; Docket No. 2022–0001; Sequence No. 4]

Submission for OMB Review; Contractor Information Worksheet; GSA Form 850

AGENCY: Identity, Credential, and Access Management (ICAM) Division, Office of Security, Office of Mission Assurance (OMA), General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a previously approved information collection requirement, with changes, expanding the coverage of the information collection of the Contractor Information Worksheet; GSA Form 850. GSA requires OMB approval for this collection to make determinations on granting unescorted physical access to GSA-controlled facilities and/or logical access to GSA-controlled information systems. The approval is critical for GSA to continue following contractor onboarding processes required for working on GSA contracts.

DATES: Submit comments on or before August 29, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments''; or by using the search function.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Ahn, Deputy Director, OMA Identity Credential and Access Management Division, GSA, telephone 202–501–2447 or via email at *phillip.ahn@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The U.S. Government conducts criminal checks to establish that applicants or incumbents working for the Government under contract may have unescorted access to federally controlled facilities. GSA uses the Contractor Information Worksheet; GSA Form 850, and digitally captured fingerprints to conduct an FBI National Criminal Information Check (NCIC) for each contractor's physical access determination to GSA-controlled facilities and/or logical access to GSA-controlled information systems. Manual fingerprint card SF–87 is used for exception cases such as contractor's significant geographical distance from fingerprint enrollment sites.

The Office of Management and Budget (OMB) Guidance M–05–24 for Homeland Security Presidential Directive (HSPD) 12, authorizes Federal departments and agencies to ensure that contractors have limited/controlled access to facilities and information systems. GSA Directive CIO P 2181.1 Homeland Security Presidential Directive-12, Personal Identity Verification and Credentialing (available at *http://www.gsa.gov/hspd12*), states that GSA contractors must undergo a minimum of an FBI National Criminal Information Check (NCIC) to receive unescorted physical access to GSA-controlled facilities and/or logical access to GSA-controlled information systems.

Contractors' Social Security Number is needed to keep records accurate, because other people may have the same name and birth date. Executive Order 9397, Numbering System for Federal Accounts Relating to Individual Persons, also allows Federal agencies to use this number to help identify individuals in agency records.

B. Annual Reporting Burden

Respondents: 25,000.
Responses per Respondent: 1.
Total Annual Responses: 25,000.
Hours per Response: .25.
Total Burden Hours: 6,250.

C. Public Comments

A 60-day notice published in the **Federal Register** at 87 FR 23863 on April 21, 2022. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0283, Contractor Information Worksheet; GSA Form 850 in all correspondence. The form can be downloaded from the GSA Forms Library at *http://www.gsa.gov/forms.* Type GSA 850 in the form search field.

Beth Anne Killoran,

Deputy Chief Information Officer.

[FR Doc. 2022–16323 Filed 7–28–22; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC or Board). This meeting is partially open to the public. There will be 15 minutes allotted for public comments at the end of the open session from 1:00 p.m. to 1:15 p.m., EDT.

DATES: The meeting will be held on August 23, 2022, from 11:00 a.m. to 1:15 p.m., EDT (OPEN); and from 1:30 p.m. to 4:30 p.m., EDT (CLOSED).

ADDRESSES: Open Session: Webinar, Atlanta, Georgia. All participants must register using the link provided to attend the open meeting: *https://dceproductions.zoom.us/meeting/register/tZYtd-iurzIvHNDz3Nb2Kl4NqksXHAhcwZnV.*

Closed Session: Teleconference.

FOR FURTHER INFORMATION CONTACT: Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway, NE, Mailstop S–1069, Atlanta, Georgia 30341; Telephone: (770) 488–1279; Email: *ncipcbsc@cdc.gov.*

SUPPLEMENTARY INFORMATION: Portions of the meeting referenced above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer,

CDC, pursuant to Public Law 92–463 (5 U.S.C. app. 2).

Purpose: The Board will: (1) conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes and strategies related to the prevention of injury and violence; (2) assist States and other entities in preventing intentional and unintentional injuries and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury.

The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. The Board provides advice on the appropriate balance of intramural and extramural research, and guidance on the needs, structure, progress, and performance of intramural programs. The Board also provides guidance on extramural scientific program matters, including the: (1) review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grant applications, cooperative agreement applications, and contract applications received in response to funding opportunity announcements as they relate to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios; and (5) review of program proposals.

Matters To Be Considered: The open session of the meeting will include discussions on an NCIPC update on Motor Vehicle Injury Prevention Research Priorities and on an NCIPC presentation on new research priorities in Drowning Prevention Research. The closed session of the meeting will focus on the Secondary Peer Review of extramural research grant applications received in response to four (4) Notices of Funding Opportunities (NOFOs): (1) RFA–CE–22–009—''Rigorous Evaluation of Community-Level Substance Use and Overdose Prevention Frameworks that Incorporate ACE-Related Prevention Strategies''; (2) RFA–CE–22–010—''Rigorous Evaluation of Strategies to Prevent Overdose through Linking People with Illicit Substance Use Disorders to Recovery Support Services''; (3) RFA–CE–22–011—''Understanding Polydrug Use Risk and Protective Factors, Patterns, and Trajectories to Prevent Drug Overdose''; and (4) RFA–CE–22–013—''Rigorous Evaluation of Community-Centered Approaches for the Prevention of Community Violence.'' Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–16335 Filed 7–28–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Lead Exposure and Prevention Advisory Committee (LEPAC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on the LEPAC. The LEPAC is composed of 15 Federal and non-Federal experts in fields associated with lead screening, prevention of lead exposure, and services for individuals and communities affected by lead exposure. Nominations are being sought for individuals with expertise in the fields of epidemiology, toxicology, mental health, pediatrics, early childhood education, special education, diet and nutrition, and environmental health. Members may be invited to serve for three-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of LEPAC objectives.

DATES: Nominations for membership on the LEPAC must be received no later than November 4, 2022. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to *LEPAC@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Paul Allwood, Ph.D., M.P.H., Designated Federal Officer, National Center for Environmental Health, CDC, 4770 Buford Highway, Atlanta, GA, 30329–4018, 770–488–6774, *PAllwood@cdc.gov.*

SUPPLEMENTARY INFORMATION: The members of this Committee are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The Committee's objective is to provide advice and recommendations to the Secretary, HHS and the Director, Centers for Disease Control and Prevention/Administrator, Agency for Toxic Substances and Disease Registry on a range of activities to include: (1) Review of Federal programs and services available to individuals and communities exposed to lead; (2) review of the current research on lead exposure to identify additional research needs; (3) review of and identification of best practices, or the need for best practices regarding lead screening and the prevention of lead exposure; (4) identification of effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Public Law 114–322 Section 2203(b) (42 U.S.C. 300j–27); and (5) undertaking of any other review or activities that the Secretary determines to be appropriate.

Annually as determined necessary by the Secretary or as required by Congress, the Committee shall submit a report to include: (1) An evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead; (2) an evaluation of additional lead exposure research needs; (3) an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead exposure; (4) input and recommendations for improved access to effective services relating to health care, education, or nutrition for individuals and communities impacted by lead exposure; and (5) any other recommendations for communities affected by lead exposure, as appropriate.

At least half of the voting committee members will consist of Federal representatives from a range of agencies that may include the Department of Housing and Urban Development; the Environmental Protection Agency; the Consumer Product Safety Commission; the Centers for Medicare and Medicaid Services; the Health Resources and Services Administration; the Food and Drug Administration; the U.S. Department of Agriculture; the Occupational Safety and Health

Administration; the National Institute of Environmental Health Sciences; the U.S. Geological Survey; and such additional federal, state, tribal, and local public and private officials as the Secretary deems necessary for the committee to carry out its function. The rest of the voting committee members will consist of non-Federal members. Only non-Federal voting members are being solicited with this announcement.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function.

Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships.

Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for LEPAC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*e.g.,* CDC, NIH, FDA, etc.)

Nominations may be submitted by the candidate him- or herself or by the person/organization recommending the candidate. The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–16336 Filed 7–28–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10464]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 29, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 (collectively, ''Affordable Care Act''), expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP).

The Centers for Medicare & Medicaid Services (CMS) recognizes the longstanding role that agents/brokers have played in connecting individuals and small businesses with health insurance products. Section 1312(e) of

the Affordable Care Act and 45 CFR 155.220(a)(1) expands the role of agents/brokers by permitting them to enroll qualified individuals or small employers/employees in qualified health plans (QHPs) through the Exchanges, and assist individuals in applying for Advance Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs). To participate as facilitators to enrollment, agents/brokers must register with the FFE, complete a training course covering eligibility and enrollment criteria for assisting in QHP enrollment, and sign agreements that formalize their understanding and commitment to adhere to the rules of the program. This requirement is specific to the FFE and does not automatically apply to State-based Exchanges (SBEs). This ICR serves as the formal request for renewal of the existing data collection. *Form Number:* CMS–10464 (OMB control number: 0938–1204); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits) *Number of Respondents:* 64,000; *Number of Responses:* 64,000; *Total Annual Hours:* 15,360. (For questions regarding this collection contact Madeline Pellish at 301–492–4390).

Dated: July 26, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–16331 Filed 7–28–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0766]

Hospira, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on May 20, 2022. The document announced the withdrawal of approval (as of June 21, 2022) of 21 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDAs after receiving withdrawal requests from Bionpharma Inc., 600 Alexander Rd., Suite 2–4B, Princeton, NJ 08540: ANDA 065301, Cefadroxil Tablets, Equivalent to (EQ) 1 gram (g) base; ANDA 065307, Cefadroxil Oral Suspension, EQ 250 milligrams (mg) base/5 milliliters (mL) and EQ 500 mg base/5 mL; ANDA 065309, Cefadroxil Capsules, EQ 500 mg base; ANDA 065326, Cephalexin Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL; from Sunny Pharmtech Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027: ANDA 203581, Glyburide Tablets, 1.25 mg, 2.5 mg, and 5 mg; and from Unicorn Pharmaceuticals, 5 Links Circle, Durham, NC, 27707: ANDA 204137, Omeprazole and Sodium Bicarbonate Capsules, 20 mg; 1.1 g. Before FDA withdrew the approval of these ANDAs, Bionpharma Inc., Sunny Pharmtech Inc., and Unicorn Pharmaceuticals informed FDA that they did not want the approval of the ANDAs withdrawn. Because Bionpharma Inc. timely requested that approval of ANDAs 065301, 065307, 065309, and 065326 not be withdrawn, the approvals are still in effect. Because Sunny Pharmtech Inc. timely requested that ANDA 203581 not be withdrawn, the approval is still in effect. Because Unicorn Pharmaceuticals timely requested that ANDA 204137 not be withdrawn, the approval is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, May 20, 2022 (87 FR 30962), in FR Doc. 2022–10924, the following correction is made:

On page 30963, in the table, the entries for ANDAs 065301, 065307, 065309, 065326, 203581, and 204137 are removed.

Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16281 Filed 7–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Special Diabetes Program for Indians

Announcement Type: New.

Funding Announcement Number: HHS–2023–IHS–SDPI–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.237.

Key Dates

Application Deadline Date: October 7, 2022.

Earliest Anticipated Start Date: January 1, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for the Special Diabetes Program for Indians (SDPI—formerly Community-Directed SDPI). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c–3. This program is described in the Assistance Listings located at *https://sam.gov/content/home/* (formerly known as the CFDA) under 93.237.

Background

Diabetes is a complex and costly chronic disease that requires tremendous long-term efforts to prevent and treat. Although diabetes is a nationwide public health problem, American Indian/Alaska Native (AI/AN) people are disproportionately affected. In 2019, 14.5 percent of AI/AN people aged 18 years or older had diagnosed diabetes, compared to 7.4 percent of non-Hispanic white people [CDC, 2021. *https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html*]. In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population [O'Connell, 2010 (*https://diabetesjournals.org/care/article/33/7/1463/39326/Racial-Disparities-in-Health-StatusA-comparison-of*); Cho, 2014 (*http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2014.301968*)]. Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

In response to the burgeoning diabetes epidemic among AI/AN people, Congress established the SDPI through the Balanced Budget Act of 1997. SDPI is a $150 million per year program that provides awards for diabetes treatment and prevention services. The IHS administers SDPI, with programmatic oversight provided by the IHS Division of Diabetes Treatment and Prevention (DDTP).

Purpose

The purpose of this program is to provide diabetes treatment and/or prevention activities and/or services (also referred to as ''activities/services'') for AI/AN communities. Awardees will implement one SDPI Diabetes Best

Practice (also referred to as ''Best Practice'') and report data on the Best Practice's Required Key Measure (RKM). Awardees may also implement other activities/services based on diabetes-related community needs and develop an evaluation plan. Activities/services will be aimed at reducing the risk of diabetes in at-risk individuals, providing high quality care to those with diagnosed diabetes, and/or reducing the complications of diabetes.

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2023 is approximately $136 million. Individual award amounts for the first budget year are anticipated to be between $12,500 and $7.5 million.

The funding formula which determines the funds available to each IHS area has been determined through Tribal consultation. Within each area, awardee Tribes provide input on the formula which determines the amount of funding available for each successful applicant.

- Current SDPI awardees should budget for the same amount as they received in FY 2022. However, funding amounts may change. See the paragraph below for additional information.
- New SDPI award applicants should apply for a $12,500 base amount.

The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards to applicants selected for funding under this announcement.

Anticipated Number of Awards

Approximately 325–450 awards will be issued under this program announcement.

Period of Performance

The period of performance is for 5 years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required of the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

A. DDTP will provide programmatic oversight, including:

1. Award Requirements

a. Create and maintain Best Practices: focused areas for improvement of diabetes prevention and treatment outcomes in communities and clinics.

b. Annual Progress Report: Create and provide instructions and template(s).

2. Data Collection and Analysis

a. IHS Diabetes Care and Outcomes Audit: Provide resources, tools, support, and training.

b. SDPI Outcomes System (SOS): Create and provide resources, tools, support, and training. Awardees will use the SOS to track and report on RKM data for their selected Best Practice.

3. Training, Communication, and Technical Assistance

a. Provide extensive SDPI award-related trainings: Topics include, Application, Annual Progress Report, and others. Most trainings are provided via live webinars. Webinars will be recorded and made available on the SDPI website based on importance.

b. Provide updates and announcements via email.

c. Maintain and update the IHS SDPI website (*https://www.ihs.gov/sdpi/*), which provides information and resources regarding this cooperative agreement, including:

i. Best Practices

ii. Additional resources—Documents and links from DDTP and the Division of Grants Management (DGM).

iii. New to SDPI—Information for new awardees and/or staff.

4. Diabetes Trainings and Resources

a. Provide diabetes-related live, recorded, and online education developed by the DDTP, designed for clinicians and other health professionals serving in the Indian health system.

b. Provide clinical updates and announcements via email.

c. Maintain and update the DDTP website, which provides additional resources for awardees including:

i. Clinician resources—online continuing education opportunities, diabetes treatment algorithms, IHS Standards of Care and Clinical Practice Recommendations for Type 2 Diabetes, and IHS Diabetes Care and Outcomes Audit resources.

ii. Patient education resources—free materials that can be ordered, printed, or downloaded from the online catalog.

B. The Indian Health Care Improvement Act, amended in 1987, established that each of the 12 IHS Areas should have an Area Diabetes Consultant (ADC). The ADCs are health care professionals with expertise in diabetes. They play a critical role in supporting SDPI diabetes treatment and prevention activities for their Area including:

1. Oversee SDPI awards within their specified Area to ensure compliance with programmatic Terms and Conditions.

2. Serve as a liaison between the SDPI award programs, DDTP, and DGM.

3. Provide training and resources to SDPI awardees. Some resources may be in the form of additional staff serving as ADC support.

4. Review or assign a designee to review annual continuation applications.

5. May serve as the Program Officer for the SDPI award programs in their IHS Area. The Program Officer is a Federal staff person who is responsible for managing and monitoring the progress of awardees in GrantSolutions. If the ADC is not eligible (*i.e.,* not Federal program staff), another individual may serve as the Program Officer in a limited capacity. Program Officer's duties include: creating funding commitments and memos, providing programmatic review/approval of amendments, and assisting in uploading documents and information as Grant Notes in GrantSolutions.

Required, Optional, and Allowable Activities

Required

All awardees will need to meet the following requirements:

1. *Activities/Services:* Awardees must provide activities/services that:

a. meet the purpose of the SDPI, which is to provide diabetes treatment and/or prevention services and activities for AI/AN communities;

b. are targeted at reducing risk factors for diabetes and diabetes-related conditions;

c. address diabetes-related issues as identified in the awardee's application; and

d. use SDPI funds as outlined in the awardee's Budget Narrative.

2. IHS Diabetes Care and Outcomes Audit (Diabetes Audit): SDPI awardees are required to participate in the Annual Diabetes Audit (*https://www.ihs.gov/diabetes/audit/*). Awardees will submit data, review results, and provide a copy of their Annual Diabetes Audit Report with their Continuation Applications. Non-clinical or community-based awardees that are not able to directly

participate in the Diabetes Audit, will need to obtain a copy of the Annual Diabetes Audit Report from their local facility or Area Diabetes Consultant (*https://www.ihs.gov/diabetes/about-us/area-diabetes-consultants-adc/*).

3. *Best Practices:* The Best Practices (*https://www.ihs.gov/sdpi/sdpi-community-directed/diabetes-best-practices/*) include the latest scientific findings and recommendations. Awardees must select one Best Practice and implement activities/services aimed at improving the associated RKM. Awardees will report on RKM data via the SOS.

4. *Collaboration:* Awardees must:

a. Consult with and accept guidance from DDTP, DGM, and their ADC/ADC Support/Federal Program Officer(s) and/or designated assignee(s).

b. Respond promptly to requests for information.

c. Attend required meetings and trainings.

d. Provide short presentations on their processes and successes, as requested.

e. Keep the entities (see item a. above) informed of emerging issues, developments, and challenges that may affect the awardee's ability to comply with the award Terms and Conditions and/or any requirements.

5. *Project Director:* Awardees must have an officially approved Project Director (approved by the Grants Management Officer in consultation with the Program Official) who has the following qualifications:

a. Relevant health or wellness education and/or experience.

b. Experience with award program management, including skills in program coordination, budgeting, reporting, and staff supervision.

c. Working knowledge of diabetes.

The Project Director should routinely update relevant SDPI award program staff with information and requirements regarding their program's activities/services.

6. *Annual Progress Report:* Per DGM policy, this report must be completed and submitted by attaching it as a Grant Note in GrantSolutions within 90 days after the end of the award program's budget period. Instructions, template(s), and other information will be posted on the SDPI Application/Report website (*https://www.ihs.gov/sdpi/sdpi-community-directed/application-reports/*).

7. *Required Trainings:* Awardees must participate in SDPI required trainings provided by DDTP. These will primarily be live webinars, which will be recorded and posted on the SDPI website for those not able to attend. Awardees will be expected to keep track of participation (both live and recorded webinars). Information about the SDPI awardee training requirements will be provided on the SDPI Grant Training website (*https://www.ihs.gov/sdpi/sdpi-community-directed/sdpi-grant-training/*).

Optional

1. *Optional Trainings:* In addition to required training, DDTP also provides optional trainings. Awardees may participate in SDPI optional trainings depending on their need for the information that will be presented. These will primarily be live webinars, which will be recorded and posted on the SDPI website for those not able to attend. Awardees are not expected to keep track of participation, but a training tracking tool is made available and updated regularly, providing all required and optional trainings hosted by DDTP for the year.

Information about the SDPI awardee training requirements will be provided on the SDPI Grant Training website (*https://www.ihs.gov/sdpi/sdpi-community-directed/sdpi-grant-training/*).

2. *Diabetes in Indian Country Conference:* DDTP occasionally hosts a conference that provides continuing education opportunities and collaboration on issues related to improving outcomes for people with diabetes and those at risk for developing diabetes. SDPI award training sessions are provided during this conference. SDPI awardee attendance is encouraged but not required.

Allowable

1. *Allowable Activities/Services:* There are many types of activities/services allowed under this award as long as they meet the activities/services requirement (see Required.1. above) and are within the scope of work defined in the Project Narrative. For questions, contact DDTP.

III. Eligibility Information

1. Eligibility

To be eligible for this FY 2023 funding opportunity, applicants must be one of the following as required by 42 U.S.C. 254c–3(b):

- An Indian health program operated by an Indian Tribe or Tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5321 *et seq.*].
- An urban Indian health program operated by an urban Indian Organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 *et seq.*].
- The Indian Health Service.

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The DGM will notify the applicant.

Additional Required Documentation

Tribes and Tribal Organizations

Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any Tribe or Tribal organization selected for funding. An applicant that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Applicants organized with a governing structure other than a Tribal

council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

Grants.gov uses a Workspace model for accepting applications. The Workspace consists of several online forms and three forms in which to upload documents—Project Narrative, Budget Narrative, and Other Documents. Give your files brief descriptive names. The filenames are key in finding specific documents during the objective review and in processing awards. Upload all requested and optional documents individually, rather than combining them into a package. Creating a package creates confusion when trying to find specific documents. Such confusion can contribute to delays in processing awards, and could lead to lower scores during the objective review.

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at *https://www.Grants.gov.*

Please direct questions regarding the application process to *DGM@ihs.gov.*

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Application forms:

1. SF–424, Application for Federal Assistance.
2. SF–424A, Budget Information—Non-Construction Programs.
3. SF–424B, Assurances—Non-Construction Programs.
4. Project Abstract Summary Form

- Project Narrative (not to exceed 18 pages). See Section IV.2.A, Project Narrative for more information.
- Budget Justification and Narrative (not to exceed 7 pages). See Section IV.2.B, Budget Narrative for instructions.
- One-page Timeframe Chart.
- 2021 and 2022 Annual Diabetes Audit reports (DRAFT report for 2022 is acceptable) or copies of Audit waivers provided by DDTP.
- Tribal Resolution(s) (Tribes and/or Tribal organizations).
- Letter(s) of Support from one or more of the following:

1. Board of Directors (Urban Indian health programs).
2. Chief Executive Officer (IHS facilities).
3. Tribes served (highly recommended for IHS facilities)

- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Key contacts form for diabetes program coordinator.
- Contractor/Consultant resumes or qualifications and scope of work (if applicable).
- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost (IDC) rate agreement (required in order to receive IDC).
- Organizational chart or written information that shows where the SDPI Program fits into the larger organization (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (not applicable to IHS facilities).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
2. Face sheets from audit reports. Applicants can find these on the FAC website at *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See *https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives and Other Programmatic Reports

A. *Project Narrative*

This narrative should be a separate document that is no more than 18 pages and must: (1) have consecutively numbered pages; (2) use black font 12 points or larger (applicants may use 10 point font for tables); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8-1/2 x 11 inches). DDTP provides an optional PDF template on the SDPI Application website at *https://www.ihs.gov/sdpi/sdpi-community-directed/application-reports/*, which applicants can use to provide the required information instead of developing their own format.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the overall page limit, the application will be considered not responsive and will not be reviewed. The 18-page limit for the narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items. Page limits for each section within the project narrative are guidelines, not hard limits.

There are six parts to the Project Narrative:

Part A: Program Identifiers/Experience (Limit—2 Pages)

Information to identify your program including past experience with diabetes treatment and preventions in AI/AN Communities (include years of experience), geographic location, food resources, and relationship or role with local Indian health clinic.

Part B: Needs Assessment (Limit—3 Pages)

Section 1: Diabetes Needs

Assessment—identify key diabetes-related health issues and diabetes prevalence.

Section 2: Review of Diabetes Audit Reports

Obtain and review of 2021 and 2022 Annual Diabetes Audit Reports to provide 2—3 items/elements that need to be improved and how your program will address those items/elements.

Section 3: Challenges

Identify and describe challenges your program experiences or may face related to prevention and/or treatment of diabetes.

Part C: Program Support and Resources (Limit—3 Pages)

Section 1: Leadership Support

Identify at least one organization administrator or Tribal leaders (other than your Program Coordinator) who has agreed to support your SDPI program for 2023 and describe how they will be actively involved with your program.

Section 2: Key Personnel

List all key personnel that will be involved in your program's activities/services. This may be your ''Diabetes Team.'' You must also separately provide a brief resume or biographical sketch for all key personnel listed.

Section 3: Partnerships and Collaborations

List current active partnerships related to your SDPI program and describe any new partnerships and collaborations that your SDPI program is planning to implement. Include information about how these partners and collaborators will contribute to the activities/services you plan to provide.

Part D: SDPI Diabetes Best Practice (Limit—3 Pages)

Section 1: Best Practice Selection

Applicants must select one Best Practice that addresses one of the needs that was identified in the needs assessment (Part B). There is a list of all the Best Practices on the Best Practices website: *https://www.ihs.gov/sdpi/sdpi-community-directed/diabetes-best-practices/.* For each Best Practice, there is a brief statement on the importance, RKM information, and guidance for selecting a Target Group, and tools and resources.

Section 2: Best Practice Activities

Provide a list of activity(ies)/service(s) to implement that would improve the RKM of the selected Best Practice. Each activity/service should include a brief description and a timeline for implementation.

Section 3: Target Group Number and Description

Awardees will be required to report RKM data for one Target Group for their selected Best Practice. A Target Group is the largest number of patients/participants that you can realistically include in the activities/services you provided in the Best Practice activities for the budget period. The following should be considered in selecting your Target Group:

a. The size and characteristics (*e.g.,* ages, health status, settings, locations) of the community or patient population that you are going to draw your Target Group from;

b. Intensity of the activities/services you plan to do; and

c. SDPI funding and other resources available to provide activities/services.

Part E: Activities/Services not related to selected Best Practice (Optional. Limit—5 Pages)

Provide information for up to five major activities/services, supported by SDPI funds, to address needs that were identified in the needs assessment (Part B). Activities/services reported here should be based on the following criteria:

a. Use the most award funding and program time.

b. Address significant needs/challenges.

Part F: Additional Information (Limit—2 Pages)

Provide additional information as specified by program office.

B. Budget Narrative (Limit—7 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs) for the first year of the project. The applicant can submit with the budget narrative a more detailed spreadsheet than is provided by the SF–424A (the spreadsheet will not be considered part of the budget narrative). The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the ''Other'' category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the additional pages should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

C. IHS Diabetes Care and Outcomes Audit

The IHS Diabetes Care and Outcomes Audit is a process to assess care and health outcomes for AI/AN people with diagnosed diabetes. IHS, Tribal, and Urban Indian health care facilities nationwide participate in this process each year by auditing medical records for their patients with diabetes. Applicants who are able to must submit copies of their local facility's 2021 and 2022 Annual Diabetes Audit reports or copies of the Audit waivers provided by DDTP.

Annual Diabetes Audit reports can be obtained in the following ways:

a. Via the WebAudit: *https://www.ihs.gov/diabetes/audit/.*

b. Request from their local facility.

c. Request from their ADC: *https://www.ihs.gov/diabetes/about-us/area-diabetes-consultants-adc/.*

For programs that received Audit waivers, these can be found in GrantSolutions (as a Grant Note).

If the applicant is unable to obtain their local facility's 2021 and 2022 Annual Diabetes Audit Reports, they must provide an explanation in their Project Narrative (Part B). For any questions, contact DDTP.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), Deputy Director, DGM, by telephone at (301) 443–2114. Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one cooperative agreement will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If you cannot submit an application through *Grants.gov*, you must request a waiver prior to the application due date. This contact must be initiated prior to the application due date or your waiver request will be denied. Prior approval must be requested and obtained from Mr. Paul Gettys, Deputy Director, DGM. You must send a written waiver request to *DGM@ihs.gov* with a copy to *Paul.Gettys@ihs.gov*. The waiver request must be documented in writing (emails are acceptable) before submitting an application by some other method, and must include clear justification for the

need to deviate from the required application submission process.

If the DGM approves your waiver request, you will receive a confirmation of approval email containing submission instructions. You must include a copy of the written approval with the application submitted to the DGM. Applications that do not include a copy of the signed waiver from the Deputy Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package at *https://www.Grants.gov* by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

System for Award Management (SAM)

Organizations that are not registered with SAM must access the SAM online registration through the SAM home page at *https://sam.gov.* United States (U.S.) organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active. Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at *https://sam.gov.*

Unique Entity Identifier

Your *SAM.gov* registration now includes a Unique Entity Identifier (UEI), generated by *SAM.gov*, which replaces the DUNS number obtained from Dun and Bradstreet. *SAM.gov* registration no longer requires a DUNS number. Check your organization's *SAM.gov* registration as soon as you decide to apply for this program. If your *SAM.gov* registration is expired, you will not be able to submit an application. It can take several weeks to renew it or resolve any issues with your registration, so do not wait.

Check your *Grants.gov* registration. Registration and role assignments in *Grants.gov* are self-serve functions. One user for your organization will have the authority to approve role assignments, and these must be approved for active users in order to ensure someone in your organization has the necessary access to submit an application.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS awardees to report information on sub-awards. Accordingly, all IHS awardees must notify potential first-tier sub-awardees that no entity may receive a first-tier sub-award unless the entity has provided its UEI number to the prime awardee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

Additional information on implementing the Transparency Act, including the specific requirements for SAM, are available on the DGM Grants Management, Policy Topics web page at *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See ''Multi-year Project Requirements'' at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Introduction and Need for Assistance (15 Points)

(i) Program Identifiers/Experience (Project Narrative Part A)

(1) Was program identifier information adequately provided?

(2) Did applicant provide sufficient information to establish their location and relationship to their local Indian Health Clinic?

(ii) Needs Assessment (Project Narrative Part B)

(1) Did the applicant adequately describe the key diabetes-related health issues identified by their community/leadership?

(2) Were numbers provided for applicant's local user population and people with diagnosed diabetes?

(3) Did the applicant appropriately identify Diabetes Audit items (or diabetes-related issues if Audit Reports were not provided) that need to be improved?

(4) Did the applicant adequately describe how they will address the Diabetes Audit items or diabetes-related issues that need to be improved?

(5) Did the applicant adequately describe challenges?

B. Project Objective(s), Work Plan and Approach (30 Points)

(i) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Did the applicant provide an adequate description of activities/services to improve the RKM?

(2) Are the activities/services proposed appropriate for the selected Best Practice and Target Group?

(3) Do the planned activities/services appear to be reasonable given the constraints of timeframe, resources, and staff?

(ii) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Do activities/services address diabetes-related issues identified in the needs assessment in Part B?

(2) Are activities/services aimed at reducing risk factors for diabetes and/or related conditions?

(3) Are activities/services adequately described?

(4) Do the planned activities/services appear to be reasonable given the constraints of timeframe, resources, and staff?

C. Program Evaluation (15 Points)

(i) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Was a Best Practice selected?

(2) Was the number of patients/participants in the Target Group provided?

(3) Was the Target Group adequately described?

(4) Are the Target Group and number of patients/participants reasonable given the information the applicant provided in their needs assessment and program resources sections?

(ii) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Was an appropriate target group identified for each activity/service?

(2) Did the applicant specify how improvement and reduction in risk factors will be evaluated?

D. Organizational Capabilities, Key Personnel, and Qualifications (30 Points)

(i) Program Identifiers/Experience (Project Narrative Part A)

(1) Does the applicant have experience with diabetes treatment and prevention services in AI/AN communities.

(2) Is the experience provided recent? (within 5 years)

(ii) Program Support (Project Narrative Part C)

(1) Does the program propose to provide sufficient and appropriate staff to carry out planned activities?

(2) Did the applicant identify an appropriate organization administrator or Tribal leader, other than the Program Coordinator, to support their SDPI program?

(3) Did the applicant describe how this leader will be involved with the SDPI program?

(4) Did the applicant provide appropriate and adequate information about key personnel in the Project Narrative?

(5) Did the applicant provide appropriate and adequate information about partnerships and collaborations in the Project Narrative?

E. Categorical Budget and Budget Justification (10 Points)

(i) Does the budget match the scope of work described in the Project Narrative?

(ii) Was each line item adequately specified and justified?

(iii) Do funding totals match between the SF–424A, budget line item, and justification?

(iv) Is the budget reasonable and realistic?

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*.

These can include:

- Work plan, logic model, and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on the evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, period of performance limit) will not be referred to the ORC and will not be funded. The program office will notify the applicant of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS DDTP within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, the budget period, and period of performance. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved But Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at *https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf.*
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at *https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.*

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

• Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75 subpart E.

E. Audit Requirements:

• Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all awardees that request reimbursement of IDC in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, ''any non-Federal entity (NFE) [*i.e.,* applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.''

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS awardees are negotiated with the Division of Cost Allocation at *https://rates.psc.gov/* or the Department of the Interior (Interior Business Center) at *https://ibc.doi.gov/ICS/tribal.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or write to *DGM@ihs.gov.*

3. Reporting Requirements

The awardee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active award, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please use the form under the Recipient User section of *https://www.grantsolutions.gov/home/getting-started-request-a-user-account/.* Download the Recipient User Account Request Form, fill it out completely, and submit it as described on the web page and in the form.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the budget period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance. Instructions, template(s), and other information will be posted on the SDPI website at *https://www.ihs.gov/sdpi/sdpi-community-directed/application-reports/.*

B. Financial Reports

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the period of performance. Awardees are responsible and accountable for reporting accurate information on all required reports: the Progress Reports and the Federal Financial Report.

C. Data Collection and Reporting

SOS RKM Data Requirements: Data for the selected Best Practice RKM will be submitted using the SOS. Awardees will submit results for their RKM for their selected Best Practice into this system at the start (baseline) and end (final) of the budget period, with the option to submit more frequently. The system will generate SOS RKM data reports to meet the SDPI outcomes reporting requirements. These results will be stored in the system and will be accessible to program staff, as needed. Awardees will need to appoint at least one person in their program to get access to and submit data into the SOS.

i. *Baseline data:* Data is to be submitted into the SOS by the last business day of February each year (*e.g.,* 2023 baseline data will be by Tuesday, February 28, 2023). A report from the SOS showing baseline data submission will be due with continuation applications.

ii. *Final data:* Data for the prior budget period is to be submitted into the SOS by the last business day of January, each year (*e.g.,* 2023 final data will be due by Wednesday, January 31, 2024). A report from the SOS showing baseline and final data submission will be due with the Annual Progress Report.

Refer to the SDPI website (*https://www.ihs.gov/sdpi/*) for the latest information on report templates, due dates, webinars and submission instructions.

Diabetes Care and Outcomes Audit: SDPI awardees are required to participate in the Annual Diabetes Audit (*https://www.ihs.gov/diabetes/audit/*). Awardees will submit data, review results, and provide a copy of their Annual Diabetes Audit Report with their annual SDPI applications. Diabetes Annual Audit data are to be submitted into the WebAudit each year around mid-March, (*e.g.,* 2023 Audit data collecting annual data will be due approximately March 15, 2023). Non-

clinical or community-based awardees, that are not able to directly participate in the Diabetes Audit, will need to obtain a copy of the Annual Diabetes Audit Report from their local facility or Area Diabetes Consultant (*https://www.ihs.gov/diabetes/about-us/area-diabetes-consultants-adc/*).

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for awardees of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards. The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation threshold met for any specific reporting period. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at *https://www.ihs.gov/dgm/policytopics/*.

E. Non-Discrimination Legal Requirements for Awardees of Federal Financial Assistance

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see *https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html* and *https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.*

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html* and *https://www.lep.gov.*
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.*
- HHS funded health and education programs must be administered in an environment free of sexual harassment. See *https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.*
- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see *https://www.hhs.gov/conscience/conscience-protections/index.html* and *https://www.hhs.gov/conscience/religious-freedom/index.html.*

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at *https://www.fapiis.gov/fapiis/#/home* before making any award in excess of the simplified acquisition threshold (currently $250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. All applicants and awardees must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Marsha Brookins, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–4750, Fax: (301) 594–0899, Email: *DGM@ihs.gov*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/*, (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGrantee Disclosures@oig.hhs.gov*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to:

Applicant's Area Diabetes Consultant: *https://www.ihs.gov/diabetes/about-us/area-diabetes-consultants-adc/*, IHS Division of Diabetes Treatment and Prevention, 5600 Fishers Lane, Mailstop: 08N34A, Rockville, MD 20857, Phone: (844) 447–3387, Fax: (301) 594–6213, Email: *diabetesprogram@ihs.gov* and *sdpi@ihs.gov*, Division of Diabetes website: *https://www.ihs.gov/diabetes/* and *https://www.ihs.gov/sdpi/*

2. Questions on grants management and fiscal matters may be directed to:

For IHS Area: Albuquerque, Donald Gooding, Grants Management Specialist, Phone: (301) 443–2298, Email: *Donald.Gooding@ihs.gov*

For IHS Areas: Nashville, Tucson, Andrew Diggs, Grants Management Specialist, Phone: (301) 443–2241, Email: *Andrew.diggs@ihs.gov*

For IHS Areas: Great Plains, Oklahoma City, Phoenix, and Portland, Cherron Smith, Grants Management Specialist, Phone: (301) 443–2192, Email: *Cherron.Smith@ihs.gov*

For IHS Areas: Alaska, Bemidji, and Billings, Patience Musikikongo, Grants Management Specialist, Phone: (301) 443–2059, Email: *Patience.Musikikongo@ihs.gov*

For Urban, Navajo, and California, Pallop Chareonvootitam, Grants Management Specialist, Phone: (301) 443–2195, Email: *Pallop.Chareonvootitam@ihs.gov*, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857

3. Questions on systems matters may be directed to:

Paul Gettys, Deputy Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114, E-Mail: *Paul.Gettys@ihs.gov*

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2022–16264 Filed 7–28–22; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2022–0042]

Faith-Based Security Advisory Council

AGENCY: The Office of Partnership and Engagement (OPE), The Department of Homeland Security (DHS).

ACTION: Notice of charter renewal with amendments.

SUMMARY: This notice announces the renewal of the Faith-Based Security Advisory Council (FBSAC) for an additional two years and amendment of its charter.

FOR FURTHER INFORMATION CONTACT: Michael J. Miron at *HSAC@hq.dhs.gov* or at 202–891–2876.

SUPPLEMENTARY INFORMATION: The Faith-Based Security Advisory Council (FBSAC) charter is established under the authority of 6 U.S.C. 451. This discretionary committee is established in accordance with and operates under the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C., Appendix. The FBSAC is renewed for an additional two years and its charter has been amended.

Amendments to the charter include:

(1) The previous charter stated that there were 25 members. It is now amended to 30 members.

(2) All FBSAC members will now serve as Representative Members, except the Member from the Department of Justice or Federal Bureau of Investigation who is appointed as a non-voting ex officio member.

(3) The previous charter allowed for members to be drawn from seven government offices. This has been amended to only include one non-voting ex officio member to be appointed from the Department of Justice of Federal Bureau of Investigation.

(4) In compliance with Executive Order 14035 on Diversity, Equity, Inclusion & Accessibility in the Federal Workforce (herein referenced as DEIA), the amended charter will state:

In order for DHS to fully leverage broad-ranging experience and education, the Council must be diverse with regard to professional and technical expertise. DHS is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

In addition to the aforementioned amendments, the renewed charter contains certain technical and organizational but non-substantive changes in terms of format and wording. For any questions regarding the amendments, please contact the individual in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: July 26, 2022.

Michael J. Miron,

Committee Management Officer, Department of Homeland Security.

[FR Doc. 2022–16272 Filed 7–27–22; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0009]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition for Nonimmigrant Worker

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until August 29, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2005–0030. All submissions received must include the OMB Control Number 1615–0009 in the body of the letter, the agency name and Docket ID USCIS–2005–0030.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief,

Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on May 22, 2022, at 87 FR 31257, allowing for a 60-day public comment period. USCIS did not receive any comment(s) in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2005–0030 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. USCIS uses the data collected on this form to determine eligibility for the requested nonimmigrant petition and/or requests to extend or change nonimmigrant status. An employer (or agent, where applicable) uses this form to petition USCIS for an alien to temporarily enter as a nonimmigrant worker. An employer (or agent, where applicable) also uses this form to request an extension of stay or change of status on behalf of the nonimmigrant worker. The form serves the purpose of standardizing requests for nonimmigrant workers and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under certain nonimmigrant employment categories. It also assists USCIS in compiling information required by Congress annually to assess effectiveness and utilization of certain nonimmigrant classifications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129 is 294,751 and the estimated hour burden per response is 2.34 hours; the estimated total number of respondents for the information collection E–1/E–2 Classification Supplement to Form I–129 is 4,760 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection Trade Agreement Supplement to Form I–129 is 3,057 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection H Classification Supplement to Form I–129 is 96,291 and the estimated hour burden per response is 2 hours; the estimated total number of respondents for the information collection H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 96,291 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection L Classification Supplement to Form I–129 is 37,831 and the estimated hour burden per response is 1.34 hours; the estimated total number of respondents for the information collection O and P Classifications Supplement to Form I–129 is 22,710 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection Q–1 Classification Supplement to Form I–129 is 155 and the estimated hour burden per response is 0.34 hours; and the estimated total number of respondents for the information collection R–1 Classification Supplement to Form I–129 is 6,635 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,072,810 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $70,681,290.

Dated: July 26, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–16337 Filed 7–28–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–39; OMB Control Number 2502–0507]

30-Day Notice of Proposed Information Collection: Annual Adjustment Factors (AAF) Rent Increase Requirement

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection

described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for additional 30 days of public comment.

DATES: *Comments Due Date:* August 29, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, PD&R, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on January 5, 2022, at 87 FR 473.

A. Overview of Information Collection

Title of Information Collection: Annual Adjustment Factors (AAF) Rent Increase Requirement.

OMB Approval Number: 2502–0507.

Type of Request: Reinstatement, with change, of previously approved collection for which approval has expired.

Form Number: HUD–92273–S8.

Description of the need for the information and proposed use: Owners of project-based section 8 contracts that utilize the AAF as the method of rent adjustment provide this information which is necessary to determine whether or not the subject properties' rents are to be adjusted and, if so, the amount of the adjustment.

Respondents: Business, not for profit institutions.

Estimated Number of Respondents: 1,080.

Estimated Number of Responses: 8.

Frequency of Response: On occasion.

Average Hours per Response: 1.5 hours.

Total Estimated Burden: 12.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2022–16270 Filed 7–28–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/A0A501010.999900 253G]

Rate Adjustments for Indian Irrigation Projects

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) owns or has an interest in irrigation projects located on or associated with various Indian reservations throughout the United States. We are required to establish irrigation assessment rates to recover the costs to administer, operate, maintain, and rehabilitate these projects. We are notifying you that we have adjusted the irrigation assessment rates at several of our irrigation projects and facilities to reflect current costs of administration, operation, maintenance, and rehabilitation.

DATES: The 2023 Irrigation Assessment Rates are effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: David Fisher, Chief, Division of Water and Power, (406) 657–5985. For details about a particular BIA irrigation project, please use the tables in the **SUPPLEMENTARY INFORMATION** section to contact the BIA regional or local office where the irrigation project is located.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rate Adjustment was published in the **Federal Register** on April 1, 2022 (87 FR 19116) to propose adjustments to the irrigation assessment rates at several BIA irrigation projects. The public and interested parties were provided an opportunity to submit written comments during the 60-day period that ended May 31, 2022.

Did BIA defer or change any proposed rate increases?

No. BIA did not defer or change any proposed rate increases.

Did BIA receive any comments on the proposed irrigation assessment rate adjustments?

Yes. BIA received nine (9) written comments related to the proposed 2023 irrigation assessment rate adjustment for the Flathead Indian Irrigation Project (FIIP). Comments were received by letter and email.

What issues were of concern to the commenters?

Comments received relate specifically to the proposed 2023 irrigation assessment rate adjustment for FIIP. BIA's summary of the issues and responses are provided below.

Comment: Commenters state a general opposition to the FIIP irrigation assessment rate adjustment and BIA's methodology for determining FIIP's budget, including a specific concern that available funds from October 2021 should be depleted and the budget should not include funding for all vacant personnel positions.

Response: As noted when rates were proposed in the **Federal Register** on April 1, 2022 (87 FR 19116), BIA is required to establish irrigation

assessment rates that recover the costs to administer, operate, maintain, and rehabilitate our projects. As owner of FIIP, it is BIA's responsibility to ensure adequate resources are made available to meet the requirements noted above. BIA's authority to assess rates is codified at 25 U.S.C. 381 *et seq.* and is addressed in BIA's regulations at 25 CFR part 171. *See also* 73 FR 11,028, 11,030 (February 29, 2008). Additionally, the repayment contracts between the respective irrigation districts and the Department of the Interior explicitly state that operation and maintenance (O&M) expenses ''shall be paid . . . as provided . . . by rules made or to be made . . . by the Secretary of the Interior.'' The procedures followed by BIA in adjusting its irrigation assessment rates are consistent with applicable law and past practice, and the methodology used by BIA to determine the O&M assessment rates for FIIP is reasonable.

The proposed 2023 irrigation assessment adjustments for FIIP's basic per acre rate categories are necessary and justified due to the increased costs associated with administering, operating, maintaining, and rehabilitating FIIP. In accordance with BIA financial guidelines and 25 CFR part 171, BIA developed the FIIP budget for 2023 expenditures and income approximately two years in advance. BIA relied on financial reports generated by the Financial and Business Management System and procurement files to review past expenditures and project a future budget. The FIIP Project Manager also used his discretion to assess and anticipate upcoming financial needs and priorities. The 2023 expenses were then divided by the total assessable acres within FIIP. The $2 per acre assessment increase for the ''basic per acre—A'' rate category is necessary to ensure FIIP can pay its anticipated expenses for 2023.

Following BIA policy, the FIIP Project Manager held two meetings in April 2022 with representatives of the Flathead Irrigation District, Mission Irrigation District, and Jocko Irrigation District to discuss the proposed 2023 irrigation assessment increase from $33.50 to $35.50 per acre. During these meetings, BIA provided details supporting the 2023 budget, justifications, and proposed O&M assessment.

Some commenters submitted a copy of FIIP's account balances as of October 2021 that did not include the account purposes or expenses. While FIIP's account balances totaled nearly $6.3 million in October 2021, this money was allocated for specific purposes and upcoming expenses. BIA irrigation projects are required to maintain a sinking fund for heavy equipment replacement and maintenance, a reserve fund for emergencies and contingencies, and funding for environmental compliance activities; $4.2 million of the $6.3 million was allocated for these purposes. Approximately $400,000 of the $6.3 million was allocated for scheduled construction activities on FIIP's aging infrastructure. The remaining $1.7 million of the $6.3 million was budgeted for 2021, 2022, and 2023 O&M expenses, including: personnel, equipment costs, acquisition costs, and materials and supplies. We believe FIIP's account balances in October 2021 were reasonable and appropriate because FIIP receives the bulk of its O&M collections twice annually, its account balance fluctuates throughout the year, and actual expenditures may vary from budgeted or estimated expenses. Although a small portion of the October 2021 available funds were intended for 2023 O&M expenses, FIIP must increase its 2023 assessment rates to avoid a deficit and ensure it has sufficient funds for the remainder of its O&M expenditures in 2023.

Regarding funding for personnel, the proposed 2023 O&M assessment does not include funding for all vacant positions. The 2023 budget includes personnel salary, benefits, and overtime for FIIP's 32 employees as well as two vacant positions. The remaining 23 vacant positions in FIIP's organizational chart are not accounted for in the 2023 budget.

Comment: Two commenters state the quality of irrigation service and water flow need to improve before assessments are increased.

Response: FIIP provides irrigation service commensurate with its resources which means the $2 per acre assessment increase is needed to improve the project's quality of service. The increased revenue will allow FIIP to fill two vacant personnel positions—one hydrologist and one civil engineer. The quality of irrigation service will improve as funding becomes available to fill additional personnel positions, while also retaining and increasing experience levels of existing FIIP staff. FIIP is actively working with the BIA Northwest Region and BIA human resources offices to fill its vacant personnel positions subject to available funding.

The FIIP rate adjustment is also needed to maintain the project's existing quality of service and assure its water delivery obligations are satisfied. Many O&M expenses are not consistent from year to year or under BIA's control, including the costs of existing personnel, pumping, materials and supplies, and repairs. Federal personnel expenses require the use of local area pay tables for General Schedule and Federal Wage System employees, maintained and managed by the Office of Personnel Management, and factor in the annual cost of living increases, annual wage board estimates, and annual overtime estimates. Power expenses for pumping are weather dependent and vary widely from year to year. And the costs of materials, supplies, and repairs are subject to depreciation and inflation.

Comment: One commenter recommends using the Confederated Salish and Kootenai Tribes' water settlement funds to pay for O&M instead of increasing assessment rates.

Response: The Montana Water Rights Protection Act (Consolidated Appropriations Act of 2021, Division DD, Pub. L. 116–260, 134 stat. 1182) authorized funds to implement the Act as well as the water rights compact entered into by the Confederated Salish and Kootenai Tribes, the State of Montana, and the United States. The Act authorizes the use of appropriated funds for certain activities, including certain rehabilitation, modernization, mitigation, reclamation, and restoration activities set forth in section 7 of the Act. The Act does not, however, authorize the use of those funds for O&M costs of FIIP.

Does this notice affect me?

This notice affects you if you own or lease land within the assessable acreage of one of our irrigation projects or if you have a carriage agreement with one of our irrigation projects.

Where can I get information on the regulatory and legal citations in this notice?

You can contact the appropriate office(s) stated in the tables for the irrigation project that serves you, or you can use the internet site for the Government Publishing Office at *www.gpo.gov.*

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior (Secretary) by 5 U.S.C. 301 and the Act of August 14, 1914 (38 stat. 583; 25 U.S.C. 385). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under Part 209, Chapter 8.1A, of the Department of the Interior's Departmental Manual.

Whom can I contact for further information?

The following tables are the regional and project/agency contacts for our irrigation facilities.

Project name	Project/Agency contacts
Northwest Region Contacts	
Bryan Mercier, Regional Director, Bureau of Indian Affairs, Northwest Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4169, Telephone: (503) 231–6702.	
Flathead Indian Irrigation Project	Larry Nelson, Acting Irrigation Project Manager, 220 Project Drive, St. Ignatius, MT 59865, Telephone: (406) 745–2661.
Fort Hall Irrigation Project	David Bollinger, Irrigation Project Manager, 36 Bannock Avenue, Fort Hall, ID 83203–0220, Telephone: (208) 238–1992.
Wapato Irrigation Project	Pete Plant, Project Administrator, 413 South Camas Avenue, Wapato, WA 98951–0220, Telephone: (509) 877–3155.
Rocky Mountain Region Contacts	
Susan Messerly, Regional Director, Bureau of Indian Affairs, Rocky Mountain Regional Office, 2021 4th Avenue North, Billings, MT 59101, Telephone: (406) 247–7943.	
Blackfeet Irrigation Project	Kenneth Bird, Acting Superintendent, Greg Tatsey, Irrigation Project Manager, P.O. Box 880, Browning, MT 59417, Telephones: (406) 338–7544 Superintendent, (406) 338–7519 Irrigation Project Manager.
Crow Irrigation Project	Clifford Serawop, Superintendent, Jim Gappa, Acting Irrigation Project Manager (BIA), (Project O&M performed by Water Users Association), P.O. Box 69, Crow Agency, MT 59022, Telephones: (406) 638–2672 Superintendent, (406) 247–7998 Acting Irrigation Project Manager.
Fort Belknap Irrigation Project	Mark Azure, Superintendent, Jim Gappa, Acting Irrigation Project Manager (BIA), (Project O&M contracted to Tribes under Pub. L. 93–638), 158 Tribal Way, Suite B, Harlem, MT 59526, Telephone: (406) 353–2901 Superintendent, (406) 353–8454 Irrigation Project Manager (Tribal Office).
Fort Peck Irrigation Project	Anna Eder, Superintendent, Jim Gappa, Acting Irrigation Project Manager (BIA), (Project O&M performed by Fort Peck Water Users Association), P.O. Box 637, Poplar, MT 59255, Telephones: (406) 768–5312 Superintendent, (406) 247–7998 Acting Irrigation Project Manager, (406) 653–1752 Lead ISO—Huber Wright.
Wind River Irrigation Project	Leslie Shakespeare, Superintendent, Jim Gappa, Acting Irrigation Project Manager (BIA), (Project O&M for Little Wind, Johnstown, and Lefthand Units contracted to Tribes under Pub. L. 93–638; Little Wind-Ray and Upper Wind Units O&M performed by Ray Canal, A Canal, and Crowheart Water Users Associations), P.O. Box 158, Fort Washakie, WY 82514, Telephones: (307) 332–7810 Superintendent, (406) 247–7998 Acting Irrigation Project Manager.
Southwest Region Contacts	
Patricia L. Mattingly, Regional Director, Bureau of Indian Affairs, Southwest Regional Office, 1001 Indian School Road NW, Albuquerque, NM 87104, Telephone: (505) 563–3100.	
Pine River Irrigation Project	Priscilla Bancroft, Superintendent, Vickie Begay, Irrigation Project Manager, P.O. Box 315, Ignacio, CO 81137–0315, Telephones: (970) 563–4511 Superintendent, (970) 563–9484 Irrigation Project Manager.
Western Region Contacts	
Jessie Durham, Acting Regional Director, Bureau of Indian Affairs, Western Regional Office, 2600 North Central Avenue, 4th Floor Mailroom, Phoenix, AZ 85004, Telephone: (602) 379–6600.	
Colorado River Irrigation Project	Davetta Ameelyenah, Superintendent, Gary Colvin, Irrigation Project Manager, 12124 1st Avenue, Parker, AZ 85344, Telephones: (928) 669–7111 Superintendent, (928) 662–4392 Irrigation Project Manager.
Duck Valley Irrigation Project	Joseph McDade, Superintendent, (Project O&M compacted to Shoshone-Paiute Tribes under Pub. L. 93–638), 2719 Argent Avenue, Suite 4, Gateway Plaza, Elko, NV 89801, Telephones: (775) 738–5165 Superintendent, (208) 759–3100 Tribal Office.
Yuma Project, Indian Unit	Denni Shields, Superintendent, (Bureau of Reclamation (BOR) owns the Project and is responsible for O&M), 256 South Second Avenue, Suite D, Yuma, AZ 85364, Telephones: (928) 782–1202 Superintendent, (928) 343–8100 BOR Area Office Manager.
San Carlos Irrigation Project (Indian Works and Joint Works).	Ferris Begay, Project Manager (BIA), Clarence Begay, Supervisory Civil Engineer (BIA), (Portions of Indian Works O&M compacted to Gila River Indian Community under Pub. L. 93–638), 13805 North Arizona Boulevard, Coolidge, AZ 85128, Telephones: (520) 723–6225 Project Manager, (520) 723–6203 Acting Supervisory Civil Engineer, (520) 562–6720 Gila River Indian Irrigation & Drainage District.
Uintah Irrigation Project	Antonio Pingree, Superintendent, Ken Asay, Irrigation System Manager (BIA), (Project O&M performed by Uintah Indian Irrigation Project Operation and Maintenance Company), P.O. Box 130, Fort Duchesne, UT 84026, Telephones: (435) 722–4300 Superintendent, (435) 722–4344 Irrigation System Manager, (435) 724–5200 Uintah Indian Irrigation Operation and Maintenance Company.
Walker River Irrigation Project	Rachael Larson, Superintendent, 311 East Washington Street, Carson City, NV 89701, Telephone: (775) 887–3501.

What irrigation assessments or charges are adjusted by this notice?

The rate table below contains final rates for the 2022 and 2023 calendar years for all irrigation projects where we recover costs of administering, operating, maintaining, and rehabilitating them. An asterisk immediately following the rate category notes the irrigation projects where 2022 rates are different from the 2023 rates.

Project name	Rate category	Final 2022 rate	Final 2023 rate
Northwest Region Rate Table			
Flathead Irrigation Project	Basic per acre—A *	$33.50	$35.50
	Basic per acre—B *	16.75	17.75
	Minimum Charge per tract	75.00	75.00
Fort Hall Irrigation Project	Basic per acre *	62.50	64.50
	Minimum Charge per tract *	40.00	41.00
Fort Hall Irrigation Project—Minor Units	Basic per acre *	41.00	45.00
	Minimum Charge per tract *	40.00	41.00
Fort Hall Irrigation Project—Michaud Unit	Basic per acre *	68.50	73.50
	Pressure per acre *	106.50	114.00
	Minimum Charge per tract *	40.00	41.00
Wapato Irrigation Project—Toppenish/Simcoe Units	Minimum Charge per bill	25.00	25.00
	Basic per acre	25.00	25.00
Wapato Irrigation Project—Ahtanum Units	Minimum Charge per bill	30.00	30.00
	Basic per acre	30.00	30.00
Wapato Irrigation Project—Satus Unit	Minimum Charge per bill	79.00	79.00
	"A" Basic per acre	79.00	79.00
	"B" Basic per acre	85.00	85.00
Wapato Irrigation Project—Additional Works	Minimum Charge per bill	80.00	80.00
	Basic per acre	80.00	80.00
Wapato Irrigation Project—Water Rental	Minimum Charge per bill *	86.00	90.00
	Basic per acre *	86.00	90.00
Rocky Mountain Region Rate Table			
Blackfeet Irrigation Project	Basic-per acre	20.50	20.50
Crow Irrigation Project—Willow Creek O&M (includes Agency, Lodge Grass #1, Lodge Grass #2, Reno, Upper Little Horn, and Forty Mile Units).	Basic-per acre *	28.50	29.00
Crow Irrigation Project—All Others (includes Bighorn, Soap Creek, and Pryor Units).	Basic-per acre *	28.50	29.00
Crow Irrigation Project—Two Leggins Unit	Basic-per acre	14.00	14.00
Crow Irrigation Two Leggins Drainage District	Basic-per acre	2.00	2.00
Fort Belknap Irrigation Project	Basic-per acre *	18.00	19.00
Fort Peck Irrigation Project	Basic-per acre *	27.00	28.00
Wind River Irrigation Project—Units 2, 3 and 4	Basic-per acre	25.00	25.00
Wind River Irrigation Project—Unit 6	Basic-per acre	22.00	22.00
Wind River Irrigation Project—LeClair District (See Note #1)	Basic-per acre	47.00	47.00
Wind River Irrigation Project—Crow Heart Unit	Basic-per acre	16.50	16.50
Wind River Irrigation Project—A Canal Unit	Basic-per acre	16.50	16.50
Wind River Irrigation Project—Riverton Valley Irrigation District (See Note #1).	Basic-per acre	30.65	30.65
Southwest Region Rate Table			
Pine River Irrigation Project	Minimum Charge per tract *	50.00	75.00
	Basic-per acre *	22.50	23.00
Western Region Rate Table			
Colorado River Irrigation Project	Basic per acre up to 5.75 acre-feet	64.00	64.00
	Excess Water per acre-foot over 5.75 acre-feet.	18.00	18.00
Duck Valley Irrigation Project	Basic per acre	5.30	5.30
Yuma Project, Indian Unit (See Note #2)	Basic per acre up to 5.0 acre-feet	157.00	(+)
	Excess Water per acre-foot over 5.0 acre-feet.	30.00	(+)
	Basic per acre up to 5.0 acre-feet (Ranch 5).	157.00	(+)

San Carlos Irrigation Project (Joint Works) (See Note #3)	Basic per acre		$26.00	$26.00
	2023 Construction Water Rate Schedule:			
		Off project construction	On project construction—gravity water	On project construction—pump water
	Administrative Fee.	$300.00	$300.00	$300.00.
	Usage Fee	$250.00 per month.	No Fee	$100.00 per acre foot.
	Excess Water Rate †.	$5.00 per 1,000 gal.	No Charge	No Charge.

Project name	Rate category	Final 2022 rate	Final 2023 rate
San Carlos Irrigation Project (Indian Works) (See Note #4)	Basic per acre *	$90.50	$99.44
Uintah Irrigation Project	Basic per acre	23.00	23.00
	Minimum Bill	25.00	25.00
Walker River Irrigation Project	Basic per acre	31.00	31.00

* Notes irrigation projects where rates are adjusted.
+ These rates have not yet been determined.
† The excess water rate applies to all water used in excess of 50,000 gallons in any one month.

Note #1: O&M rates for LeClair and Riverton Valley Irrigation Districts apply to Trust lands that are serviced by each irrigation district. The annual O&M rates are based on budgets submitted by LeClair and Riverton Valley Irrigation Districts, respectively.

Note #2: The O&M rate for the Yuma Project, Indian Unit has two components. The first component of the O&M rate is established by the Bureau of Reclamation (BOR), the owner and operator of the Project. BOR's rate, which is based upon the annual budget submitted by BOR is $153.00 for 2022 but has not been established for 2023. The second component of the O&M rate is established by BIA to cover administrative costs, which includes billing and collections for the Project. The 2022 BIA rate component is $4.00/acre. The final 2023 BIA rate component is $4.00/acre.

Note #3: The Construction Water Rate Schedule identifies fees assessed for use of irrigation water for non-irrigation purposes.

Note #4: The O&M rate for the San Carlos Irrigation Project—Indian Works has three components. The first component is established by BIA San Carlos Irrigation Project—Indian Works, the owner and operator of the Project; the 2022 rate is $56.50 per acre, and the final 2023 rate is $56.50 per acre. The second component is established by BIA San Carlos Irrigation Project—Joint Works; the 2022 rate is $26.00 per acre, and the final 2023 rate is $26.00 per acre. The third component is established by the San Carlos Irrigation Project Joint Control Board (comprised of representatives from the Gila River Indian Community and the San Carlos Irrigation and Drainage District); the 2022 rate is $8.00 per acre, and 2023 rate is $16.94 per acre.

Consultation and Coordination With Tribal Governments (Executive Order 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this notice under the Department's consultation policy and under the criteria of Executive Order 13175 and have determined there to be substantial direct effects on federally recognized Tribes because the irrigation projects are located on or associated with Indian reservations. To fulfill its consultation responsibility to Tribes and Tribal organizations, BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of water delivery, water availability, and costs of administration, operation, maintenance, and rehabilitation of projects that concern them. This is accomplished at the individual irrigation project by project, agency, and regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of our overall coordination and consultation process to provide notice to, and request comments from, these entities when we adjust irrigation assessment rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

These rate adjustments are not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Regulatory Planning and Review (Executive Order 12866)

These rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

These rate adjustments are not a rule for the purposes of the Regulatory Flexibility Act because they establish ''a rule of particular applicability relating to rates.'' 5 U.S.C. 601(2).

Unfunded Mandates Reform Act of 1995

These rate adjustments do not impose an unfunded mandate on state, local, or Tribal governments in the aggregate, or on the private sector, of more than $130 million per year. They do not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, the Department is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Takings (Executive Order 12630)

These rate adjustments do not affect a taking of private property or otherwise have ''takings'' implications under Executive Order 12630. The rate adjustments do not deprive the public, State, or local governments of rights or property.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, these rate adjustments do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because they will not

affect the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This notice complies with the requirements of Executive Order 12988. Specifically, in issuing this notice, the Department has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct as required by section 3 of Executive Order 12988.

Paperwork Reduction Act of 1995

These rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0141 and expires January 31, 2023.

National Environmental Policy Act

The Department has determined that these rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370(d)), pursuant to 43 CFR 46.210(i). In addition, the rate adjustments do not present any of the 12 extraordinary circumstances listed at 43 CFR 46.215.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–16324 Filed 7–28–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–XXX–L19100000.BJ0000.LRCSEX902800; MO#4500162376]

Notice of Proposed Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed official filing.

SUMMARY: The plats of surveys for the lands described in this notice are scheduled to be officially filed 30 calendar days after the date of this publication in the BLM Montana State Office, Billings, Montana. The surveys, which were executed at the request of the United States Forest Service Office, Ashland Ranger District, Montana are necessary for the management of these lands.

DATES: A person or party who wishes to protest this decision must file a notice of protest in time for it to be received in the BLM Montana State Office no later than August 29, 2022.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Joshua Alexander, BLM Chief Cadastral Surveyor for Montana; telephone: (406) 896–5123; email: *jalexand@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Alexander. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Principal Meridian, Montana

T. 5 S., R. 46 E.

Secs. 20, 21, 27 thru 30, and 32 thru 36.

T. 6 S., R. 47 E.

Secs. 7, 17, 18, 19, and 20.

A person or party who wishes to protest an official filing of a plat of survey identified earlier must file a written notice of protest with the BLM Chief Cadastral Surveyor for Montana at the address listed in the **ADDRESSES** section of this notice. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be received in the BLM Montana State Office no later than the date described in the **DATES** section of this notice; If received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM Chief Cadastral Surveyor for Montana within 30 calendar days after the notice of protest is received.

If a notice of protest of the plat(s) of survey is received prior to the scheduled date of official filing or during the 10 calendar day grace period provided in 43 CFR 4.401(a) and the delay in filing is waived, the official filing of the plat(s) of survey identified in the notice of protest will be stayed pending consideration of the protest. Upon receipt of a timely protest, and after a review of the protest, the Authorized Officer will issue a decision either dismissing or otherwise resolving the protest. A plat of survey will then be officially filed 30 days after the protest decision has been issued in accordance with 43 CFR part 4.

If a notice of protest is received after the date described in the **DATES** section of this notice and the 10-calendar-day grace period provided in 43 CFR 4.401(a), the notice of protest will be untimely, may not be considered, and may be dismissed.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

Joshua F. Alexander,

Chief Cadastral Surveyor for Montana.

[FR Doc. 2022–16322 Filed 7–28–22; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT929000–223–L14400000.BJ0000; MO#4500162461]

Notice of Proposed Filing of Plats of Survey; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed official filing.

SUMMARY: The plats of surveys for the lands described in this notice are scheduled to be officially filed 30 calendar days after the date of this publication in the BLM Montana State Office, Billings, Montana. The surveys, which were executed at the request of the United States Bureau of Reclamation, Rapid City Field Office, Rapid City, South Dakota and are necessary for the management of these lands.

DATES: A person or party who wishes to protest this decision must file a notice

of protest in time for it to be received in the BLM Montana State Office no later than August 29, 2022.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM South Dakota State Office, 5001 Southgate Drive, Billings, Montana 59101, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Joshua Alexander, BLM Chief Cadastral Surveyor for South Dakota; telephone: (406) 896–5123; email: *jalexand@blm.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Alexander. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Black Hills Meridian, South Dakota

T. 8 N., R. 2 E.
Sec. 2.
T. 9 N., R. 2 E.
Secs. 35 and 36.

A person or party who wishes to protest an official filing of a plat of survey identified earlier must file a written notice of protest with the BLM Chief Cadastral Surveyor for South Dakota at the address listed in the **ADDRESSES** section of this notice. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be received in the BLM Montana State Office no later than the date described in the **DATES** section of this notice; If received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM Chief Cadastral Surveyor for South Dakota within 30 calendar days after the notice of protest is received.

If a notice of protest of the plat(s) of survey is received prior to the scheduled date of official filing or during the 10 calendar day grace period provided in 43 CFR 4.401(a) and the delay in filing is waived, the official filing of the plat(s) of survey identified in the notice of protest will be stayed pending consideration of the protest. Upon receipt of a timely protest, and after a review of the protest, the Authorized Officer will issue a decision either dismissing or otherwise resolving the protest. A plat of survey will then be officially filed 30 days after the protest decision has been issued in accordance with 43 CFR part 4.

If a notice of protest is received after the date described in the **DATES** section of this notice and the 10-calendar-day grace period provided in 43 CFR 4.401(a), the notice of protest will be untimely, may not be considered, and may be dismissed.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

Joshua F. Alexander,

Chief Cadastral Surveyor for South Dakota.

[FR Doc. 2022–16321 Filed 7–28–22; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT929000–212–L14400000.BJ0000; MO#4500152973]

Notice of Proposed Filing of Plats of Survey; North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed official filing.

SUMMARY: The plats of surveys for the lands described in this notice are scheduled to be officially filed 30 calendar days after the date of this publication in the BLM Montana State Office, Billings, Montana. The surveys, which were executed at the request of the Chief, Fluids Adjudication Section, Montana State Office, Bureau of Land Management, Billings Montana are necessary for the management of these lands.

DATES: A person or party who wishes to protest this decision must file a notice of protest in time for it to be received in the BLM Montana State Office no later than August 29, 2022.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Joshua Alexander, BLM Chief Cadastral Surveyor for North Dakota; telephone: (406) 896–5123; email: *jalexand@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Alexander. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Fifth Principal Meridian, North Dakota

T. 148 N., R. 97 W.
Secs. 28 and 33.

A person or party who wishes to protest an official filing of a plat of survey identified earlier must file a written notice of protest with the BLM Chief Cadastral Surveyor for North Dakota at the address listed in the **ADDRESSES** section of this notice. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be received in the BLM Montana State Office no later than the date described in the **DATES** section of this notice; If received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM Chief Cadastral Surveyor for North Dakota within 30 calendar days after the notice of protest is received.

If a notice of protest of the plat(s) of survey is received prior to the scheduled date of official filing or during the 10 calendar day grace period provided in 43 CFR 4.401(a) and the delay in filing is waived, the official filing of the plat(s) of survey identified in the notice of protest will be stayed pending consideration of the protest. Upon receipt of a timely protest, and after a review of the protest, the Authorized Officer will issue a decision either dismissing or otherwise resolving the protest. A plat of survey will then be officially filed 30 days after the protest decision has been issued in accordance with 43 CFR part 4.

If a notice of protest is received after the date described in the **DATES** section of this notice and the 10-calendar-day grace period provided in 43 CFR 4.401(a), the notice of protest will be untimely, may not be considered, and may be dismissed.

Before including your address, phone number, email address, or other

personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

Joshua F. Alexander,

Chief Cadastral Surveyor for North Dakota.

[FR Doc. 2022–16320 Filed 7–28–22; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L16100000.DQ0000.LXLUGSEM0000. LLUTPO1000]

Notice of Intent To Prepare a Resource Management Plan for the Grand Staircase-Escalante National Monument in Utah and an Associated Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and Presidential Proclamation 10286, the Bureau of Land Management (BLM) Utah State Director intends to revise a Resource Management Plan (RMP) with an associated Environmental Impact Statement (EIS) for the Grand Staircase-Escalante National Monument (GSENM) and by this notice is announcing the beginning of the scoping period to solicit public comments and identify issues, is providing the planning criteria for public review, and is issuing a call for nominations for areas of critical environmental concern (ACECs). The RMP revision would replace the existing 2020 GSENM RMP and 2020 Kanab-Escalante Planning Area RMP.

DATES: The BLM requests the public submit comments concerning the scope of the analysis, potential alternatives, and identification of relevant information, studies, and ACEC nominations by September 27, 2022. To afford the BLM the opportunity to consider this information and ACEC nominations raised by commenters in the Draft RMP/EIS, please ensure your comments are received prior to the close of the 60-day scoping period or 15 days after the last public meeting, whichever is later.

The BLM also requests the public submit comments on the planning criteria by the same date identified above. The planning criteria will be made available to the public within the first 30 days of the 60-day comment period to ensure the public has at least 30 days to comment on the planning criteria as required by the planning regulations at 43 CFR 1610.2(e). To afford the BLM the opportunity to consider this information and ACEC nominations raised by commenters in the Draft RMP/EIS, please ensure your comments are received prior to the close of the 60-day scoping period or 15 days after the last public meeting, whichever is later.

ADDRESSES: You may submit comments on issues and planning criteria related to the GSENM RMP and nominations of new ACECs by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2020343/510*
- *Mail:* ATTN: GSENM RMP Project Manager, BLM Paria River District, 669 S Highway 89A, Kanab, UT 84741

Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2020343/510* and at the BLM Paria River District Office, 669 US–89A, Kanab, Utah 84741.

FOR FURTHER INFORMATION CONTACT: Scott M. Whitesides, Project Manager, telephone 801–539–4054; address Bureau of Land Management Utah, 440 West 200 South Suite 500, Salt Lake City, Utah 84101; email *swhitesides@blm.gov.* Contact Mr. Whitesides to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Whitesides. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Utah State Director intends to prepare an RMP with an associated EIS for GSENM, announces the beginning of the scoping process, seeks public input on issues and relevant planning criteria, and invites the public to nominate ACECs. The planning area is located in Kane and Garfield counties and encompasses approximately 1.87 million acres of public land.

Purpose and Need for the RMP

This RMP will provide a management framework, including goals, objectives, and management direction, to guide Monument management. Purposes and needs serve to frame issue identification, alternatives development, and effects analyses. The following purposes and desired outcomes are set forward explicitly in Presidential Proclamation 10286 or have been identified based on key present and historical GSENM management challenges. Planning for these desired outcomes will be crucial for development of an RMP that provides direction for addressing critical management challenges. Associated needs and challenges that the RMP will address are also summarized.

1. Protect and restore the entirety of the large, remote, rugged, and markedly impenetrable landscapes, including dark skies and natural soundscapes. The Monument's fundamental values and objects include a rich mosaic of objects of natural, historic, and scientific interest.

Needs and challenges: The immense scale and unspoiled naturalness of the Monument serves as a foundation for the rest of the Monument objects and values, including the diversity of ecotypes and extent and diversity of geological and paleontological resources, vegetation, and wildlife. Through the latter half of the 20th century, Utah's large extent of unspoiled natural, roadless areas was unique in the lower 48 states, ultimately providing for the 1996 GSENM proclamation. Monument visitation is steadily increasing, mostly due to recreational use. International and regional tourism is rising, and Utah is the state with the fastest growing population in the last decade (18.4%); in 2021 Utah's growth was 1.7% while the national population growth was 0.1%. These increases in human presence pose diverse challenges to preservation of resources (*e.g.,* vegetation and soil impacts, loss of potential for human solitude, adverse effects on certain wildlife species, increases in noise). Effects such as these tend to be incremental, and gradual degradation of resources over time can easily occur, almost unnoticed, without adequate management sidebars, as well as overall management goals and objectives for the landscape as a whole. Avoidance of incremental degradation, so that the unique value of a largely unspoiled, natural landscape is retained given ongoing multiple uses, warrants substantial consideration in the planning process.

2. Emphasize the Monument as a living, outdoor laboratory to be used for diverse and significant research and discovery related to the Monument's varied resources, objects, and values.

Needs and challenges: The proclamation that originally designated the Monument in 1996 explained, ''Even today, this unspoiled natural area remains a frontier, a quality that greatly enhances the monument's value for scientific study.'' However, the circumstances surrounding and within the Monument have changed substantially in the past 25 years (see purpose *1,* above). There are substantial management challenges regarding how to maintain the unspoiled naturalness, which is essential to the Monument's purposes of science. Given the intensification of anthropogenic change in the world, natural refugia on the scale of this Monument are increasingly essential, rare, and hard to maintain. Areas such as the Monument are a cornerstone for scientific understanding of the past, and they are equally important for understanding changes and trends that allow us to appropriately plan for the future.

3. Protect and restore biological resources including five life zones, a variety of habitats, and multiple eco-regions, due largely to the remoteness and substantial variation in elevation and topography of the Monument. The Monument contains unique and isolated plant communities, various floristic communities, relic and endemic plants, diverse wildlife including unique species of invertebrates, and a biodiversity of bees, as well as amphibians, birds, and mammals including mountain lion and desert bighorn sheep.

Needs and challenges: Management of living individuals, populations, and interconnected communities and ecosystems must address a spectrum of needs and challenges. The Monument supports a range of ecotypes, as well as remnant, relic, and refugia populations across the landscape's substantial ranges of elevation and large geographic extent. Additionally, climate change and drought are outside the historic range of variability, affecting vegetation and thereby habitat and species. A key component of this planning effort will be identification of appropriate management for changing ecotypes and populations, especially given the scientific emphasis of this Monument.

4. Protect and restore the historical and cultural understanding and appreciation related to Monument objects and values. These objects and values include an exceedingly high density of archaeological sites, modern tribal uses, numerous historic routes and trails including Powell expedition routes and Mormon pioneer trails, historic inscriptions, ghost towns, cowboy line camps, and historic townsites.

This topic focuses on restoration, retention, and education/appreciation of historic and cultural resources.

Needs and challenges: Protection, restoration, identification, and appreciation of such objects and values often requires substantial on-the-ground work, such as inventories, stabilization work, and sometimes development of educational interpretive materials. The RMP planning process should clarify how to select and prioritize such efforts, as well as consider the role of collaboration with outside entities and consultation with Tribal Nations that could both (1) further the aims of understanding and appreciation of these resources and (2) support the work of protection and restoration.

5. Protect the Monument's varied geology and associated scenery with numerous unique areas and features and abundant, important paleontological resources. The entire landscape affords extraordinary visual landscapes and rich geologic and world-class paleontological resources. Reasonably accommodate challenges of remote paleontological research (e.g., transport of large fossils).

Needs and challenges: Extensive scenic exploration can be accessed via paved roads, which serve as the main arteries through the Monument. Paved roads are augmented by several maintained, unpaved roads and some lesser dirt roads. Scenic geology itself, and the opportunity for visual appreciation, is relatively easy to preserve, while other uses of these resources, for example scientific study and personal collection, will require consideration during planning in order to provide for appropriate access, use, and protection. This is important in view of the scientific purposes of the Monument.

6. Protect and restore world-class outdoor recreation opportunities, including hiking and backpacking, hunting, canyoneering, mountain biking, and horseback riding associated with a substantial, regional socioeconomic sector. Serve visitors via several visitor centers with diverse emphases, as well as provide basic facilities to ensure human health and safety (e.g., restrooms).

Needs and challenges: The majority of the direct human visitation to the Monument is recreational. While not identified as an object in need of protection, Proclamation 10286 acknowledges the world class recreational opportunities within the monument that support a travel and tourism sector that is a source of economic opportunity for the region. However, high and increasing levels of recreational visitation are a top management challenge, and appropriate management of recreational use is a central concern to be addressed by the RMP. Large numbers of visitors can degrade visitor experience, raise human safety and health issues (such as related to human waste), and may harm ecologically sensitive areas and species. Challenges in finding a balance between Proclamation objectives and rapidly rising visitation levels means that use quotas or other mitigating management actions will be considered. Additionally, substantial step-down recreation planning is needed, such as for Special Recreation Management Areas. Yet such planning has never occurred on the Monument due to the substantial time and resources it requires.

7. Protect and restore Monument objects and values within a multiple-use context. Monument lands have served multiple-use purposes since Anglo settlement in what is now the State of Utah. Such uses include, for example, grazing, hunting, and recreating. Monument lands were a combination of BLM and Utah School and Institutional Trust Lands Administration lands prior to Monument designation. Some of these lands were being used related to mining, rock hounding for alabaster, and other purposes.

Needs and challenges: Since the time of Monument designation in 1996, controversy and disputes have existed among stakeholders regarding BLM's discretionary uses. Such controversy spans the spectrum of use: allowing for uses such as mining and livestock grazing while also supporting conservation and recreation uses and promoting strong preservation interests. Establishing management that ensures protection of monument objects and values and serves other monument purposes while accommodating other uses, as appropriate, is vital in this planning process.

Preliminary Alternatives

The BLM will be analyzing alternatives that explore and evaluate different ways of achieving the purpose and need listed above. The alternatives will explore different outcomes to be addressed during this planning effort to understand the trade-offs of different land management approaches. The BLM welcomes comments on all preliminary

alternatives as well as suggestions for additional alternatives.

Planning Criteria

The planning criteria guide the planning effort and lay the groundwork for effects analysis by identifying the preliminary issues and their analytical frameworks. Preliminary issues for the planning area have been identified by BLM personnel and from early engagement conducted for this planning effort with Federal, State, and local agencies; Tribes; and other stakeholders. The BLM has identified several preliminary issues for this planning effort's analysis and will provide them for public review as part of the planning criteria within the timeframe identified in **DATES** above. The planning criteria are available for public review and comment at the ePlanning website (see **ADDRESSES**).

Summary of Expected Impacts

Consistent with protection of GSENM objects identified in Proclamation 10286, implementation of a new RMP may impact, either beneficially or adversely, resources and uses within GSENM, including recreation, livestock grazing, soils, water, vegetation, cultural and historic resources, paleontological resources, visual resources, designated areas, social and economic values, and other human and environmental resources. Planning decisions related to livestock grazing will also consider portions of Glen Canyon National Recreation Area because portions of livestock grazing allotments administered by the BLM cross these administrative boundaries.

Schedule for the Decision-Making Process

The BLM will provide additional opportunities for public participation consistent with NEPA and land use planning processes, including a 90-day comment period on the Draft RMP/EIS and a concurrent 30-day public protest period and a 60-day Governor's consistency review on the Proposed RMP. The Draft RMP/EIS is anticipated to be available for public review in the spring of 2023, and the Proposed RMP/Final EIS is anticipated to be available for public protest of the Proposed RMP in late 2023 with an Approved RMP and Record of Decision in spring 2024.

Public Scoping Process

This notice of intent initiates the scoping period and public review of the planning criteria, which guide the development and analysis of the Draft RMP/EIS.

The BLM will be holding a total of five scoping meetings. Two scoping meetings will be held virtually. Three scoping meetings will be conducted in-person: one in Kanab, one in Escalante, and a third meeting held at a yet-to-be-determined location. Details of all meetings will be announced once known. In compliance with Department of the Interior public health guidelines, the BLM may need to hold public meetings in a virtual format if county-level transmission of COVID–19 is ''high'' at the time of the public meetings. In that case, the BLM will hold five virtual public meetings.

The specific dates and locations of these scoping meetings will be announced at least 15 days in advance through local media, social media, and the ePlanning website (see **ADDRESSES**).

The ePlanning website (see **ADDRESSES**) also includes, or will include background information on GSENM, a planning process overview, preliminary planning criteria and interim management guidance. You may submit comments on issues, potential alternatives, relevant information and analyses, and the preliminary planning criteria in writing to the BLM at any public scoping meeting or to the BLM using one of the methods listed in the **ADDRESSES** section.

ACECs

There are currently no designated ACECs within GSENM because the BLM determined under the previous planning efforts that the management provided through those RMPs were sufficient without warranting the designation of ACECs. No areas were identified during preplanning and early engagement for consideration as ACECs.

This notice invites the public to nominate areas for ACEC consideration. To assist the BLM in evaluating nominations for consideration in the Draft RMP/EIS, please provide supporting descriptive materials, maps, and evidence of the relevance and importance of resources or hazards by the close of the public scoping period to facilitate timely evaluation (see **DATES** and **ADDRESSES**). The BLM has identified the anticipated issues related to the consideration of ACECs in the planning criteria.

Cooperating Agencies

Federal, State, and local agencies, along with Tribal Nations may request or be asked by the BLM to participate as a cooperating agency. At this time the BLM has identified the following potential cooperating agencies:

- National Park Service
- United States Fish and Wildlife Service
- USDA Forest Service
- Utah's Public Lands Policy Coordinating Office
- State of Utah School and Institutional Trust Lands Administration
- Utah State Historic Preservation Office
- Kane County, Utah
- Garfield County, Utah
- Washington County Water Conservancy District
- Kaibab Band of Paiute Indians
- Navajo Nation
- Paiute Indian Tribe of Utah
- Pueblo of Acoma
- Pueblo of San Felipe
- Pueblo of Tesuque
- Pueblo of Zuni
- San Juan Southern Paiute Tribe of Arizona
- Hopi Tribe
- Ute Indian Tribe of the Uintah and Ouray Reservation

Responsible Official

The Utah State Director is the deciding official for this planning effort.

Nature of Decision To Be Made

The nature of the decision to be made will be the State Director's selection of land use planning decisions for managing BLM-administered lands under the principles of multiple use and sustained yield in a manner that best addresses the purpose and need.

Interdisciplinary Team

The BLM will use an interdisciplinary approach to develop the plan in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in this planning effort: cultural resources, Native American concerns, paleontology, minerals, lands/access, recreation, special designations, wildlife, livestock grazing, soils, water resources, vegetation, rangeland management, fisheries, fire management, woodlands/forestry, socioeconomics, environmental justice, visual resources, night sky, soundscapes, air quality, and climate change.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed plan and all analyzed alternatives and, in accordance with 40 CFR 1502.14(f), include appropriate mitigation measures not already included in the proposed plan or alternatives. Mitigation may

include avoidance, minimization, rectification, reduction or elimination over time, and compensation; it may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA and land use planning processes for this planning effort to help support compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including the public involvement requirements of Section 106. The information about historic and cultural resources and threatened and endangered species within the area potentially affected by the proposed plan will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM MS 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts on cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that may be interested in or affected by the proposed GSENM RMP that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency. The BLM intends to hold a series of government-to-government consultation meetings. The BLM will send invitations to potentially affected Tribal Nations prior to the meetings. The BLM will provide additional opportunities for government-to-government consultation during the NEPA process.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9 and 43 CFR 1610.2)

Gregory Sheehan,

State Director.

[FR Doc. 2022–16296 Filed 7–28–22; 8:45 am]

BILLING CODE 4331–25–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1244]

Certain Batteries and Products Containing Same; Notice of a Commission Final Determination of Violation of Section 337; Issuance of a General Exclusion Order; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended, in the above-captioned investigation. The Commission has issued a general exclusion order (''GEO'') barring entry of certain batteries and products containing same that infringe the patents asserted in this investigation. The Commission has terminated this investigation.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 5, 2021, under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''Section 337''), based on a complaint filed by One World Technologies, Inc. (''One World'') and Techtronic Power Tools Technology Ltd. (''TTT'') (collectively, ''Complainants''). 86 FR 8379–80 (Feb. 5, 2021). The complaint, as supplemented, alleges a violation of Section 337 based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain batteries and products containing same by reason of infringement of the sole claims of U.S. Patent Nos. D579,868 (''the '868 patent''); D580,353 (''the '353 patent''); and D593,944 (''the '944 patent''). *Id.* at 8379. The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation (''NOI'') names thirteen (13) respondents: Darui Development Limited (''Darui Development''); Dongguan Xinjitong Electronic Technology Co., Ltd. (''Dongguan Electronic''); Shenzhen Laipaili Electronics Co., Ltd.; Shenzhen MingYang Creation Electronic Co., Ltd.; Shenzhen Rich Hao Yuan Energy Technology Co., Ltd. (''Shenzhen Rich Hao''); Shenzhen Runsensheng Trading Co., Ltd.; Shenzhen Saen Trading Co., Ltd. (''Shenzhen Saen''); Shenzhen Shengruixiang E-Commerce Co., Ltd.; Shenzhen Uni-Sun Electronics Co., Ltd.; and Shenzhen Vmartego Electronic Commerce Co., Ltd. (collectively, the ''Defaulted Respondents''); Shenzhen Liancheng Weiye Industrial Co., Ltd.; Shenzhen Ollop Technology Co. Ltd.; and Shenzhen Tuo Yu Technology Co., Ltd. *Id.* The Office of Unfair Import Investigations (''OUII'') is participating in this investigation. *Id.*

On May 17, 2021, Commission terminated the investigation based upon the withdrawal of the complaint with respect to respondents Shenzhen Liancheng Weiye Industrial Co., Ltd., Shenzhen Ollop Technology Co. Ltd., and Shenzhen Tuo Yu Technology Co., Ltd., after Complainants were unable to serve these respondents with copies of the Complaint and NOI. Order No. 7 (Apr. 21, 2021), *unreviewed by* Notice (May 17, 2021).

On April 20, 2021, Complainants filed a motion for an order to show cause why the remaining ten (10) named respondents (*i.e.,* the Defaulted Respondents) should not be found in default after failing to respond to the Complaint and NOI, which had been duly served upon them. On May 4, 2021, the motion was granted and an order to show cause was issued. Order No. 8 (May 4, 2021). On June 3, 2021, after they failed to respond to the order to show cause, ALJ issued an ID finding all ten Defaulted Respondents to be in default. Order No. 9 (June 3, 2021), *unreviewed by* Notice (June 23, 2021).

On June 21, 2021, Complainants moved for a summary determination of violation of Section 337 by the Defaulted Respondents and for a recommended determination recommending entry of a GEO and a bond at the rate of 100 percent during the Presidential review period. Complainants did not request issuance of any cease and desist orders.

On July 16, 2021, OUII filed a response to Complainants' motion supporting a finding of summary

determination against only four (4) of the Defaulted Respondents: Darui Development, Dongguan Electronic, Shenzhen Rich Hao, and Shenzhen Saen. Specifically, OUII argued Complainants did not sufficiently connect the importation, sale, or sale after importation of certain of the Accused Products to the Defaulted Respondents. Otherwise, OUII stated it generally supports a finding that Complainants have satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(A) and (B) (19 U.S.C. 1337(a)(3)(A), (B)) and also supports Complainants' remedy requests.

On March 25, 2022, the presiding administrative law judge (''ALJ'') issued an initial determination (Order No. 15) granting in part and denying in part Complainants' motion for summary determination. The ID finds that Complainants have shown by reliable, probative, and substantial evidence that a violation of Section 337 has occurred with respect to the Asserted Patents as to the following four Defaulted Respondents: Darui Development, Dongguan Electronic, Shenzhen Rich Hao, and Shenzhen Saen. The ID finds that no violation has been established as to any other respondent. The ALJ's recommended determination on remedy and bonding (''RD'') recommends issuance of a GEO with respect to the asserted patents. The RD does not recommend issuance of any cease and desist order.

On April 6, 2022, OUII petitioned for review of certain aspects of the subject ID. No other petitions or responses to petitions were filed.

On May 11, 2022, the Commission determined to review the subject ID in part. *See* 87 FR 29879–80 (May 17, 2022). Specifically, the Commission determined to review the ID's finding regarding the economic prong of the domestic industry requirement and requested briefing. *Id.* at 29880. In addition, the Commission determined to review in part the ID for the limited purpose of making certain corrections in the ID. *Id.* The Commission also requested written submissions on remedy, the public interest, and bonding. *Id.*

On May 25, 2022, Complainants and OUII filed their opening written submissions on the issue under review and on remedy, the public interest, and bonding. On June 1, 2022, OUII filed a reply remedy submission. No other submissions were received by the Commission.

Having reviewed the submissions filed in response to the Commission notice, *see id.,* and the evidentiary record, the Commission has determined to affirm the ID's finding of a violation of Section 337 in this investigation. The Commission has also determined that the appropriate form of relief in this investigation is a GEO prohibiting the unlicensed importation of certain batteries and products containing same that infringe the '868 patent, the '353 patent, and the '944 patent.

The Commission has further determined that the public interest factors enumerated in Subsection (d)(1) (19 U.S.C. 1337(d)(1)) do not preclude issuance of the above-referenced remedial order. Finally, the Commission has determined that a bond in the amount of one hundred (100) percent of the entered value is required to permit temporary importation of the articles in question during the period of Presidential review (19 U.S.C. 1337(j)). The investigation is terminated.

The Commission's order and the record upon which it based its determination were delivered to the President and to the United States Trade Representative on the day of their issuance. The Commission has also notified the Secretary of the Treasury of the order.

The Commission vote for this determination took place on July 25, 2022.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: July 25, 2022.

Katherine M. Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–16262 Filed 7–28–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1239]

Certain Gabapentin Immunoassay Kits and Test Strips, Components Thereof, and Methods Therefor; Notice of Commission Determination To Issue a Limited Exclusion Order Against Defaulting Respondent; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a limited exclusion order against Kappa City Biotech, SAS of Montlucon, France (''Kappa City''). The Commission has also determined to impose a bond equal to one hundred (100) percent of the entered value of the infringing products imported during the period of Presidential review. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On January 25, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by ARK Diagnostics, Inc. of Fremont, California (''ARK''). *See* 86 FR 6918–19. The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor by reason of infringement of certain claims of U.S. Patent Nos. 8,828,665 and 10,203,345. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names fourteen respondents, including Kappa City; Healgen Scientific, LLC of Houston, Texas; 12PanelMedical, Inc. of Sarasota, Florida; Acro Biotech, Inc. of Rancho Cucamonga, California; AlcoPro, Inc. of Knoxville, Tennessee; American Screening, LLC of Shreveport, Louisiana; Chemtron Biotech Co., Ltd. of San Diego, California; Confirm Biosciences, Inc. of San Diego, California; Hangzhou All Test Biotech Co., Ltd. of Hangzhou, China; Mercedes Medical, LLC of Lakewood Ranch, Florida; TransMed Co., LLC of Alpharetta, Georgia; Transmetron, Inc. of Salt Lake City, Utah; Zhejiang Orient Gene Biotech Co., Ltd. of Huzhou, China; and Shanghai Chemtron Biotech

Co., Ltd. of Shanghai, China (''Shanghai Chemtron''). *See id.* The complaint and notice of investigation were later amended to add two respondents, 12Panel Now, Inc. and Hospital Connect, Inc., both of Boynton Beach, Florida. Order No. 8 (March 9, 2021), *unreviewed by* 86 FR 16640–41 (March 30, 2021).

The Commission previously terminated six respondents based on consent orders. Order Nos. 11 and 12 (Mar. 31, 2021), *unreviewed by* Comm'n Notice (Apr. 15, 2021) (TransMed Co., LLC, 12PanelMedical, Inc., 12Panel Now, Inc., and Hospital Connect, Inc.); Order No. 14 (April 9, 2021), *unreviewed by* Comm'n Notice (Apr. 22, 2021) (Mercedes Medical, LLC); Order No. 15 (April 12, 2021), *unreviewed by* Comm'n Notice (May 12, 2021) (Transmetron Inc.). The Commission also previously terminated four respondents based on settlement agreements. Order No. 13 (Apr. 5, 2021), *unreviewed by* Comm'n Notice (Apr. 19, 2021) (Confirm Biosciences, Inc.); Order No. 17 (May 5, 2021), *unreviewed by* Comm'n Notice (May 18, 2021) (AlcoPro, Inc.); Order No. 18 (May 20, 2021), *unreviewed by* Comm'n Notice (June 21, 2021) (American Screening, LLC); Order No. 29 (Jan. 31, 2022), *unreviewed by* 87 FR 11096–98 (Feb. 28, 2022) (Shanghai Chemtron). The Commission also terminated five respondents based on partial withdrawal of the complaint. Order No. 20 (June 4, 2021), *unreviewed by* Comm'n Notice (June 28, 2021) (Chemtron Biotech, Inc.); Order No. 21 (June 14, 2021), *unreviewed by* Comm'n Notice (July 1, 2021) (Hangzhou AllTest Biotech Co., Ltd.; Acro Biotech, Inc.; Zhejiang Orient Gene Biotech Co, Ltd.; Healgen Scientific, LLC).

On May 18, 2021, the Commission determined not to review an initial determination (Order No. 16) finding Kappa City in default. Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm'n Notice (May 18, 2021).

On December 7, 2021, ARK filed a declaration seeking immediate entry of a limited exclusion order and cease and desist order against Kappa City.

On February 22, 2022, the Commission determined not to review an initial determination granting a motion to terminate Shanghai Chemtron based on settlement. *See* Order No. 29 (Jan. 31, 2022), *unreviewed by* 87 FR 11096–98 (Feb. 28, 2022). The Commission concurrently determined that ARK's declaration was moot given the termination of the final remaining non-defaulting respondent in this investigation. 87 FR at 11097. The Commission also requested briefing on the issues of remedy, bonding, and the public interest. *Id.*

On March 8, 2022, ARK filed the sole response to the Commission's request for briefing. No replies or other submissions were received.

Upon review of the record, including ARK's submission, and in the absence of any response from Kappa City or from other interested persons or government agencies, the Commission has determined to issue a limited exclusion order against Kappa City pursuant to section 337(g)(1). The Commission has determined not to issue a cease and desist order against Kappa City, which is a foreign respondent. *See, e.g., In the Matter of Certain Powered Cover Plates,* Inv. No. 337–TA–1124, Comm'n Op. at 24–28 (July 10, 2020); *Certain Earpiece Devices and Components Thereof,* Inv. No. 337–TA-1121, Comm'n Op. at 42–44 (Nov. 9, 2019); *Certain Electric Skin Care Devices, Brushes and Chargers Therefore, and Kits Containing the Same,* Inv. No. 337–TA–959, Comm'n Op. at 28–33 (Feb. 13, 2017). The Commission has determined that the public interest factors do not preclude issuance of the remedial order. The Commission has further determined to set a bond in the amount of one hundred (100) percent of the entered value of the covered products imported during the period of Presidential review (19 U.S.C. 1337(j)). The Commission's order was delivered to the President and the United States Trade Representative on the day of its issuance. The investigation is hereby terminated.

Commissioners Schmidtlein and Karpel would issue both a limited exclusion order and a cease and desist order against Kappa City pursuant to section 337(g)(1) because all requirements of this provision are met. 19 U.S.C. 1337(g)(1)(A)–(E). Specifically, Kappa City was named in the complaint and was served the complaint and notice of investigation. *See* Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm'n Notice (May 18, 2021). Kappa City failed to show good cause why it should not be held in default for failing to respond to the complaint and notice of investigation. *See id.* These findings satisfy subsections 337(g)(1)(A)–(D). ARK requested a limited exclusion order and a cease and desist order against Kappa City satisfying subsection 337(g)(1)(E). Given that subsections 337(g)(1)(A)–(E) are satisfied, the statute directs the Commission to issue the requested limited exclusion order and cease and desist order, subject to consideration of the public interest. Commissioners Schmidtlein and Karpel find that issuance of the requested relief would not adversely impact the public interest factors.

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the complainant complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The Commission vote for this determination took place on July 25, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 25, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–16261 Filed 7–28–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1020]

Importer of Controlled Substances Application: Usona Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Usona Institute has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before August 29, 2022. Such persons may also file a written request for a hearing on the application on or before August 29, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal,

which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 27, 2022, Usona Institute, 2780 Woods Hollow Road, Room 2412, Fitchburg, Wisconsin 53711–5370, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Dimethyltryptamine ...	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

The institute plans to import the listed controlled substances to be used for research and analytical purposes. The materials will not be used for clinical trials or bulk manufacture. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–16338 Filed 7–28–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection

AGENCY: Laboratory Division-RSU, Federal Bureau of Investigation, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Laboratory Division-RSU, Federal Bureau of Investigation, Department of Justice, is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until September 27, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Libby Stern, Research Chemist, Federal Bureau of Investigation Laboratory Division, Research and Support Unit, 2501 Investigation Ave, Quantico, VA 22135, *geophysics@fbi.gov,* 703–632–7825.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

➢ Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Federal Bureau of Investigation, Laboratory Division-RSU, including whether the information will have practical utility;

➢ Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

➢ Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

➢ Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection*: New collection.

2. *The Title of the Form/Collection*: Metal Detector Use in Crime Scene Investigations

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection*: FBI IRB number 644–22. The applicable component within the Department of Justice is the Federal Bureau of Investigation, Laboratory Division-RSU.

4. *Affected public who will be asked or required to respond, as well as a brief abstract*: Federal Government, State, Local or Tribal Government. Those completing the questionnaires are either active or retired law enforcement personnel. This research study consists of a questionnaire to gather information on the applications metal detectors for law enforcement at crime scene investigations. Participants will be asked what were the composition of law enforcement targets and the environment which they are searching for said targets. An objective of the questionnaire is to learn if advance methods of detection were used to identify suspected targets such as a ground penetrating radar or magnetometer. The results may be published and used to understand applications of metal detectors by law enforcement at crime scenes.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond*: We expect no more than 100 individuals completing the questionnaire. On average, we expect an average of 10–15 minutes to complete the questionnaire.

6. *An estimate of the total public burden (in hours) associated with the collection*: 25 hours.

If additional information is required contact: Robert Houser, Assistant Director, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 26, 2022.

Robert Houser,

Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–16330 Filed 7–28–22; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–NEW]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; New Collection

AGENCY: Laboratory Division-RSU, Federal Bureau of Investigation, Department of Justice

ACTION: 60-Day notice.

SUMMARY: The Laboratory Division-RSU, Federal Bureau of Investigation, Department of Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 27, 2022

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Libby Stern, Research Chemist, Federal Bureau of Investigation Laboratory Division, Research and Support Unit, 2501 Investigation Ave, Quantico, VA 22135, *geophysics@fbi.gov,* 703–632–7825.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

➢ Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Federal Bureau of Investigation, Laboratory Division-RSU, including whether the information will have practical utility;

➢ Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

➢ Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

➢ Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* Law Enforcement Use of Geophysical Methods.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* FBI IRB number 645–22. The applicable component within the Department of Justice is the Laboratory Division-RSU, Federal Bureau of Investigation.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Federal Government, State, Local or Tribal Government. This questionnaire is to gather information from active and retired law enforcement on the applications of geophysical methodologies, such as ground penetrating radar (GPR) and magnetometers, to detect concealed targets (for example: homicide graves, drugs, or weapons) as part of criminal investigations. The respondents will give insight on who performed the geophysical surveys, the suspected targets, the survey environment, along with summaries of 1 to 3 geophysical surveys conducted. The results may be published and used to understand practical uses of geophysical methods for law enforcement investigations.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We expect no more than 100 individuals completing the questionnaire. On average we expect an average of 10–15 minutes to complete the survey.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 25 hours.

If additional information is required contact: Robert Houser, Assistant Director, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE, 3E.206, Washington, DC 20530.

Dated: July 22, 2022.

Robert Houser,

Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–16327 Filed 7–28–22; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 25, 2022, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Colorado in the lawsuit entitled *United States and State of Colorado* v. *DCP Operating Company, LP, et al.,* Civil Action No. 1:22–cv–01829–NRN.

The United States and the State of Colorado jointly filed this lawsuit under the Clean Air Act against Defendants DCP Operating Company, LP; DCP Midstream Holding, LLC; DCP LP Holdings, LLC; DCP Partners Colorado LLC; DCP Assets Holding, LP; and DCP Lucerne 2 Plant LLC, alleging violations of leak detection and repair requirements at seven natural gas processing plants in Colorado. The complaint seeks injunctive relief and civil penalties for the defendants' alleged failures to monitor and repair leaking equipment across the seven natural gas processing plants. The consent decree requires the defendants to perform injunctive relief to address the alleged violations, implement a mitigation project to help offset excess emissions caused by the alleged violations, and pay a $3,250,000 civil penalty. The civil penalty will be split evenly between the United States and the State of Colorado.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Colorado* v. *DCP Operating Company, LP, et al.,* D.J. Ref. No. 90–5–2–1–12335. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the

consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $23.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–16259 Filed 7–28–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modification of Consent Decree Under the Comprehensive Environmental Response Compensation and Liability Act

On July 1, 2022, the Department of Justice lodged a proposed Modification of Consent Decree with the United States District Court for the Western District of Pennsylvania in the lawsuit entitled *United States and the Territory of American Samoa* v. *Starkist Co. and Starkist Samoa Co.,* Civil Action No. 2:17 CV 01190–DSC.

The proposed Modification of Consent Decree pertains to a consent decree entered by the United States District Court for the Western District of Pennsylvania, Pittsburgh Division on March 7, 2018, (''Modification''), which resolved claims arising under sections 301(a) and 311(j) of the Clean Water Act, 42 U.S.C. 7412, sections 312 and 313 of the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. 11022 and 11023, and section 3010 of the Resource Conservation and Recovery Act, 42 U.S.C. 6930, and the regulations promulgated under those statutes. The Modification would, among other things, require Starkist Co. and Starkist Samoa, Co. to achieve and maintain compliance with the effluent limits in its National Pollution Discharge Elimination System (NPDES) permit in an alternative manner than that set forth in the original consent decree.

Pursuant to 28 U.S.C. 50.7, the United States will publish a notice of the lodging of the proposed Modification of the consent decree in the **Federal Register**. The date that notice is published will open a 30-day period for public comment on the proposed Modification of the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Territory of American Samoa* v. *StarKist Co.* and Starkist Samoa Co., D.J. Ref. No. 90–5–1–1–11357. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Modification may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* An unofficial translation of the Modification is available along with the official English version on our website. O loo i la matou laupepa o upega tafa'ilagi se faaliliuga e le'i faaaloa'ia o le Teuteuga faatasi ma lona tusitusiga i le gagana Peretania. We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–16341 Filed 7–28–22; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2022–058]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is proposing to request that the Office of Management and Budget (OMB) renew approval of an information collection our Office of Government Information Services (OGIS) uses to obtain customer intake information and consent as part of its mediation services program. OGIS collects customer name, contact information, case number, information on the customer's concern areas/resolution goals, and documents relating to the underlying Freedom of Information Act/Privacy Act request or appeal as part of its intake process in order to provide mediation services. In some cases, customers also complete a privacy consent form, NA Form 10003, authorizing OGIS to make inquiries on the customer's behalf and authorizing agencies to release to OGIS information and records related to their FOIA/Privacy Act requests and appeals. We invite you to comment on this proposed information collection.

DATES: We must receive written comments on or before September 27, 2022.

ADDRESSES: Send comments to Paperwork Reduction Act Comments (MP), Room 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, or email them to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301–837–1694 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) whether we need the proposed information collection to properly perform our agency functions; (b) our estimate of the burden of the proposed information collection and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses. We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. In this notice, we solicit comments concerning the following information collection:

Title: Freedom of Information Act (FOIA) Request for Assistance and Consent.

OMB number: 3095–0068.

Agency form number: NA Form 10003.

Type of review: Regular.

Affected public: Individuals or households, business or other for-profit,

not-for-profit institutions, and Federal Government.

Estimated number of respondents: 3,676.

Estimated time per response: Ten minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 609 hours (3,646 responses × 10 minutes/by 60 = 608 and 30 responses × 2 minutes/by 60 = 1).

Abstract: In order to fulfill its Government-wide statutory mission to mediate FOIA disputes between requesters and agencies, OGIS must communicate with Government departments and agencies regarding the customer's Freedom of Information Act (FOIA)/Privacy Act of 1974 request or appeal. As a result, OGIS collects intake information from customers who request OGIS's mediation services. This information includes the customer's name, contact information, FOIA case number, information on the customer's concern areas/resolution goals, and documents relating to the underlying Freedom of Information Act/Privacy Act request or appeal. Customers provide this information by phone, fax, email, or mail.

OGIS and other agencies must handle FOIA and Privacy Act-protected case information in conformity with the requirements of the FOIA and Privacy Act, including 5 U.S.C. 552a(b), which prohibits agencies from releasing Privacy Act-protected information without an already-established routine use or consent of the person to whom the information pertains. In accord with this requirement, a subset of customers also must fill out a privacy consent form, NA Form 10003, if dealing with an agency that has not published a system of records notice with a routine use for release of information to OGIS.

OGIS uses the information customers provide in this information collection to contact customers, request information on the customer's case from other Federal agencies, and provide the requested assistance. Without the information submitted in the intake process and the consent form, OGIS would be unable to get the information from other agencies or fulfill its mediation mission.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2022–16266 Filed 7–28–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Strategy's Subcommittee on Technology, Innovation and Partnerships hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, August 3, 2022, from 10:00–11:00 a.m. EDT.

PLACE: This meeting will be held at the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed

MATTERS TO BE CONSIDERED: The agenda is: Subcommittee Chair's Opening Remarks; Regional Innovation Engine Competition Update; FY 2023 Budget Scenarios for the TIP Directorate and Programmatic Implications.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–16456 Filed 7–27–22; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB) hereby gives notice of the scheduling of meetings for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, August 3, 2022, from 1:00 p.m.–5:45 p.m., and Thursday, August 4, 2022, from 9:00 a.m.–2:30 p.m. EDT.

PLACE: These meetings will be held at NSF headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314, and by videoconference. To attend in-person, please email your name as it appears on your photo ID, along with your affiliation, at least 24 hours in advance to *nationalsciencebrd@nsf.gov.* If the COVID status for Alexandria, Virginia remains ''medium'' or goes to ''high,'' please fill out and bring OMB's certification of vaccination form with you. Visitors who are not vaccinated or refuse to divulge their vaccination status will not be admitted. All open sessions of the meeting will be webcast live on the NSB YouTube channel.

August 3, 2022: *https://youtu.be/xz85K4mCmSs.*

August 4, 2022: *https://youtu.be/DS6jsZexews.*

STATUS: Parts of these meetings will be open to the public. The rest of the meetings will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Wednesday, August 3, 2022

Plenary Board Meeting

Open Session: 1:00 p.m.–3:35 p.m.

- NSB Chair's Remarks
- NSF Director's Remarks
  - Cool Science presentations
- Discussion with Under Secretary for Science and Innovation, US Department of Energy, Geraldine Richmond
- Antarctic Science Strategy

Closed Session: 3:35 p.m.–5:45 p.m.

- Antarctic Science Strategy
- NSB Chair's Remarks
- Approval of Prior Closed Meeting Minutes
- NSF Director's Remarks
  Agency Operating Status
- Research Security Update
- Vote to Enter Executive Plenary Closed
- Executive Plenary Closed
  - NSB Chair's Opening Remarks
- Approval of Prior Meeting Minutes
- Director's Remarks, including organizational updates

Thursday, August 4, 2022

Plenary Board

Open Session: 9:00 a.m.–10:05 a.m.

- NSB Chair Welcome and Remarks
- NSF Director's Remarks
  Senior Staff Updates
  OLPA Update Information Item
- Committee and Working Group Reports
  - Committee on Oversight
  - Committee on External Engagement
  - Committee on Science and Engineering Policy
  - Socioeconomic Status Working Group

Closed Session: 12:15 p.m.–1:55 p.m.

- NSB Chair's Opening Remarks
- Committee Reports
- Committee on Awards and Facilities Report
  - MAGLab Vote
  - NOIRLab Vote
  - RCRV Vote
  - SAGE–GAGE Vote
  - LCCF Vote
- Committee on Strategy Report
- Subcommittee on Technology, Innovation, and Partnerships Report

Open Session: 2:05 p.m.–2:30 p.m.

- NSB Chair's Activities
- NSB 2023 Meeting Dates Vote
- Approval of Prior Meeting Minutes
- NSB Chair's Closing Remarks
- NSF Director's Closing Remarks

Meeting Adjourns: 2:30 p.m.

PORTIONS OPEN TO THE PUBLIC:

Wednesday, August 3, 2022

1:00 p.m.–3:35 p.m. Plenary NSB

Thursday, August 4, 2022

9:00 a.m.–10:05 a.m. Plenary NSB
2:05 p.m.—2:30 p.m. Plenary NSB

PORTIONS CLOSED TO THE PUBLIC:

Wednesday, August 3, 2022

3:35 p.m.–5:45 p.m. Plenary NSB, including executive closed items

Thursday, August 4, 2022

12:15 p.m.–1:55 p.m. Plenary NSB

Members of the public are advised that the NSB provides some flexibility around start and end times. A session may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next session will start no later than 15 minutes after the noticed start time. If a session ends early, the next meeting may start up to 15 minutes earlier than the noticed start time. Sessions will not vary from noticed times by more than 15 minutes.

CONTACT PERSON FOR MORE INFORMATION: The NSB Office contact is Chris Blair, *cblair@nsf.gov,* 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490. Please refer to the NSB website for additional information: *https://www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–16455 Filed 7–27–22; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board's Awards and Facilities Committee hereby gives notice of the scheduling of a meeting for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Tuesday, August 2, 2022, from 2:00–5:00 p.m., and Wednesday, August 3, 2022, from 10:00–11:00 a.m., EDT.

PLACE: This meeting will be held at the National Science Foundation, 2415 Eisenhower Ave., Alexandria, VA, 22314.

STATUS: Closed

MATTERS TO BE CONSIDERED: The agenda of the August 2, 2022, meeting is: Committee Chair's Opening Remarks; Schedule of Future Information, Context, and Action Items; Action Item: Inclusion of Leadership-Class Computing Facility (LCCF) in a Future MREFC Budget; Action Item: Authorization to Increase the Total Project Cost for the Construction of the Regional Class Research Vessels (RCRV); Action Item: Authorization to Increase the Cost Cap of the Awards for Operations of the Seismological Facility for the Advancement of Geoscience (SAGE) and Geodetic Facility for the Advancement of Geoscience (GAGE); Action Item: Renewal of Award for Operations of NSF's National Optical-Infrared Astronomy Research Laboratory (NOIRLab).

The agenda of the August 3, 2022, meeting is: Action Item: Renewal of Award for Operations of NSF's National High Magnetic Field Laboratory (NHMFL or Mag Lab).

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Michelle McCrackin, *mmccrack@nsf.gov,* (703) 292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–16362 Filed 7–27–22; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Service Contract Inventory; Notice of Availability

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The Division of Acquisition and Cooperative Support within the National Science Foundation (NSF) is publishing this notice to advise the public of the availability of its Fiscal Year (FY) 2021 Service Contracts Inventory Analysis Report.

FOR FURTHER INFORMATION CONTACT: Raymond McCollum, Policy Branch Chief, Division of Acquisition and Cooperative Support, National Science Foundation. Phone: 703–292–4225; email: *rmccollu@nsf.gov.*

SUPPLEMENTARY INFORMATION: NSF's FY 2021 Service Contract Inventory Analysis Report is included as part of a governmentwide service contract inventory. The inventory includes covered service contracts that were awarded in FY 2021. The NSF analyzes this data for the purpose of determining whether its contract labor is being used in an effective and appropriate manner and if the mix of federal employees and contractors in the agency is effectively balanced. The report does not include contractor proprietary or sensitive information.

The FY 2021 Service Contract Inventory Analysis Report is provided at the following link: *https://www.nsf.gov/bfa/dcca/contracts/index.jsp.*

Authority: 42 U.S.C. 1861, *et seq.*

Dated: July 26, 2022.

Raymond L. McCollum,

Policy Branch Chief, National Science Foundation.

[FR Doc. 2022–16303 Filed 7–28–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0130]

High Energy Arcing Fault Hazard Frequency and Consequence Modeling

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft NUREG–2262, ''High Energy Arcing Fault Frequency and Consequence Modeling.''

DATES: Submit comments by August 29, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0130. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gabriel J. Taylor, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0781, email: *Gabriel.Taylor@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0130 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0130.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The draft NUREG–2262 ''High Energy Arcing Fault Frequency and Consequence Modeling'' is available in ADAMS under Accession No. ML22158A071.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0130 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC Office of Nuclear Regulatory Research and the Electrical Power Research Institute (EPRI) are advancing the understanding and state-of-practice for modeling High Energy Arcing Faults (HEAF) in fire Probabilistic Risk Assessment. NUREG/CR–6850 and NUREG/CR–6850 Supplement 1 provide the basic methods to analyze the risk associated with HEAFs in power distribution equipment (switchgear and load centers) and bus ducts (including iso-phase bus ducts), respectively. Since the publication of these two reports, the state of knowledge of the HEAF phenomena has advanced significantly. A thorough understanding of the nuclear power plant electrical distribution system and its performance during faulted conditions along with a review and categorization of industry events has occurred. Additionally, experimentation—including full scale testing on HEAF-susceptible equipment, small scale testing, and hazard estimation have increased the understanding of parameters that affect the dimensions of the zone of influence (ZOI).

In draft NUREG–2262 titled, ''High Energy Arcing Fault Frequency and Consequence Modeling,'' the NRC worked with the EPRI to combine previous HEAF-related research, methods, and data to improve realism in calculating plant risk due to HEAFs. Ignition frequency and non-suppression estimates are updated with the most recently available industry operating experience. The ZOI configurations are expanded. Previous guidance postulated one ZOI for each category of equipment (switchgear and load centers, bus ducts, and iso-phase bus ducts). The development and use of HEAF hazard estimation tools allowed for the expansion of ZOI configurations by using scenario specific parameters such as fault current magnitude, arc voltage, duration, location, electrode composition, and type of equipment, to more accurately predict the ZOI. The ZOIs results are grouped by the working group to determine consensus ZOIs for the three classes of equipment with varying levels of detail commensurate with potential risk significance.

The information contained within the draft research information letter is expected to be used in the future as the state-of-the-art method for characterizing the risk to nuclear facilities from a HEAF.

Dated: July 25, 2022.

For the Nuclear Regulatory Commission.

Mark H. Salley,

Chief, Fire and External Hazards Analysis Branch, Division of Risk Analysis, Office of Nuclear Regulatory Research.

[FR Doc. 2022–16238 Filed 7–28–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0202]

Information Collection: Safeguards on Nuclear Material, Implementation of US/IAEA Agreement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Safeguards on Nuclear Material, Implementation of US/IAEA Agreement.''

DATES: Submit comments by August 29, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–

0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0202 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0202.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The final supporting statement is available in ADAMS under Accession No. ML22165A166.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Safeguards on Nuclear Material, Implementation of US/IAEA Agreement.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 15, 2022 (87 FR 14585).

1. *The title of the information collection:* Part 75 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Safeguards on Nuclear Material, Implementation of US/IAEA Agreement.''
2. *OMB approval number:* 3150–0055.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* Selected licensees are required to provide reports of nuclear material inventory and flow for selected facilities under the US/IAEA Safeguards Agreement, permit inspections by International Atomic Energy Agency Agreement (IAEA) inspectors, complementary access of IAEA inspectors under the Additional Protocol, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of nuclear material. Reporting is done when specified events occur. Recordkeeping for nuclear material accounting and control information is done in accordance with specific instructions.
6. *Who will be required or asked to respond:* Licensees required to report information required by the U.S. Additional Protocol. Licensed possessors of nuclear material outside facilities in the U.S. Caribbean Territories.
7. *The estimated number of annual responses:* 22 (12 reporting responses + 10 recordkeepers).
8. *The estimated number of annual respondents:* 10.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 3,234.
10. *Abstract:* 10 CFR part 75, requires selected licensees to provide reports of nuclear material inventory and flow for selected facilities under the US/IAEA Safeguards Agreement, permit inspections by IAEA inspectors, complementary access of IAEA inspectors under the Additional Protocol, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of nuclear material. In addition, this collection is being renewed to include approximately 6 entities subject to the U.S.–IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366). These licensees will provide reports of nuclear material inventory and flow for entities under the U.S.–IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366), permit inspections by IAEA inspectors, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of nuclear material. These licensees will also follow written material accounting and control procedures, although actual reporting of transfer and material balance records to the IAEA will be done through the U.S. State system (Nuclear Materials Management and Safeguards System, collected under OMB clearance numbers 3150–0003, 3150–0004, 3150–0057, and 3150–0058). The NRC needs this information to implement its responsibilities under the US/IAEA agreement.

Dated: July 26, 2022.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–16315 Filed 7–28–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of August 1, 8, 15, 22, 29, September 5, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of August 1, 2022

There are no meetings scheduled for the week of August 1, 2022.

Week of August 8, 2022—Tentative

There are no meetings scheduled for the week of August 8, 2022.

Week of August 15, 2022—Tentative

There are no meetings scheduled for the week of August 15, 2022.

Week of August 22, 2022—Tentative

There are no meetings scheduled for the week of August 22, 2022.

Week of August 29, 2022—Tentative

There are no meetings scheduled for the week of August 29, 2022.

Week of September 5, 2022—Tentative

There are no meetings scheduled for the week of September 5, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 27, 2022.

For the Nuclear Regulatory Commission.

Monika G. Coflin,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2022–16419 Filed 7–27–22; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0181]

Information Collection: Packaging and Transportation of Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Packaging and Transportation of Radioactive Material.''

DATES: Submit comments by August 29, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0181 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0181.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The final supporting statement and part 71 of title 10 of the *Code of Federal Regulations* (10 CFR) burden spreadsheet are available in ADAMS under Accession Nos. ML22138A184 and ML22138A186.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to

include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Packaging and Transportation of Radioactive Material.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 15, 2022 (87 FR 14587).

1. *The title of the information collection:* 10 CFR part 71 ''Packaging and Transportation of Radioactive Material.''

2. *OMB approval number:* 3150–0008.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* On occasion. Application for package certification may be made at any time. Required reports are collected and evaluated on a continuous basis as events occur.

6. *Who will be required or asked to respond:* All NRC specific licensees who place byproduct, source, or special nuclear material into transportation, and all persons who wish to apply for NRC approval of package designs for use in such transportation.

7. *The estimated number of annual responses:* 611.

8. *The estimated number of annual respondents:* 225.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 30,619 hours (25,913 hours reporting + 4,575 hours recordkeeping + 131 hours third-party disclosure).

10. *Abstract:* The NRC regulations in 10 CFR part 71 establish requirements for packaging, preparation for shipment, and transportation of licensed material, and prescribe procedures, standards, and requirements for approval by NRC of packaging and shipping procedures for fissile material and for quantities of licensed material in excess of Type A quantities. The NRC collects information pertinent to 10 CFR part 71 for three reasons: to issue a package approval; to ensure that any incidents or package degradation or defect are appropriately captured, evaluated and if necessary, corrected to minimize future potential occurrences; and to ensure that all activities are completed using an NRC-approval quality assurance program.

Dated: July 26, 2022.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–16316 Filed 7–28–22; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–93, OMB Control No. 3235–0087]

Submission for OMB Review; Comment Request: Extension: Rule 15Bc3–1 and Form MDSW, Withdrawal From Registration of Municipal Securities Dealers

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15Bc3–1 (17 CFR 240.15Bc3–1) and Form MSDW (17 CFR 249.1110) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15Bc3–1 provides that a notice of withdrawal from registration with the Commission as a bank municipal securities dealer must be filed on Form MSDW. The Commission uses the information contained in Form MSDW in determining whether it is in the public interest to permit a bank municipal securities dealer to withdraw its registration. This information is also important to the municipal securities dealer's customers and to the public because it provides, among other things, the name and address of a person to contact regarding any of the municipal securities dealer's unfinished business.

Based upon past submissions of two filings in 2019, zero filings in 2020, zero filings in 2021, and zero filings so far in 2022, the Commission estimates that approximately one respondent will use Form MSDW annually, with a total hour burden for all respondents of approximately 1 hour per year (0.5 hours rounded up to 1 hour). This estimate is based on the Commission staff's experience in administering the form. The form is available from the Commission, and can usually be completed by checking appropriate boxes and writing the name and address of the bank municipal securities dealer, and the name and address of the person who has or will have custody of the bank municipal securities dealer's books and records. The staff estimates that the average internal compliance cost per hour is approximately $406.[1] Therefore, the estimated total annual internal cost of compliance is approximately $203 per year (0.5 hours/year × $406/hour = $203/year).

Rule 15Bc3–1 does not contain an explicit recordkeeping requirement, but the instructions for filing Form MSDW state that an exact copy should be retained by the registrant. Providing the information on the application is mandatory in order to withdraw from registration with the Commission as a bank municipal securities dealer. The information contained in the notice will not be kept confidential.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by August 29, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

[1] The estimate of $406 per hour is for a compliance attorney, based on the Securities Industry and Financial Markets Association's Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

July 25, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16258 Filed 7–28–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95361; File No. SR–NYSECHX–2022–17]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee Schedule

July 25, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 12, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fee Schedule (the ''Fee Schedule'') related to colocation to remove obsolete text. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule related to colocation to remove obsolete text.[4]

(1) Proposal To Change Names of Select Third Party Systems and Third Party Data Feeds

As set forth in the Fee Schedule, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[5] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Fee Schedule.

The Exchange proposes to amend the list of Third Party Systems in the Fee Schedule to reflect the following updated names for existing Third Party Systems:

- Change the name of the ''Miami International Securities Exchange'' to ''MIAX Options,'' and
- Change the name of the ''MIAX PEARL'' to ''MIAX PEARL Options.''

The Exchange also proposes to amend the list of Third Party Data Feeds in the Fee Schedule to reflect the following updated names for existing Third Party Data Feeds:

- Change the name ''Miami International Securities Exchange/MIAX PEARL'' to ''MIAX Options/MIAX PEARL Options;'' and
- Change ''SR Labs—SuperFeed'' data feeds to ''Vela—SuperFeed,'' to reflect the content provider's recent change to the name of these products.

This change would update the names of these services, but would not make any change to the services provided.

(2) Proposal To Delete Discontinued Third Party Data Feed

The Exchange proposes to delete the ''NASDAQ OMDF'' data feed from the list of available Third Party Data Feeds, as it is no longer offered by the content service provider.

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–30, SR–NYSEAMER–2022–31, SR–NYSEArca–2022–41, and SR–NYSENAT–2022–12.

[5] *See* Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–27).

(3) Proposal To Remove References to ICE Data Global Index

The Exchange proposes to remove obsolete references to the ICE Data Global Index (the ''GIF'') from the list of Third Party Data Feeds available for connectivity and related text.

In May 2020, ICE, which publishes the GIF, announced to its customers that before the end of 2020, it would cease offering the GIF as a stand-alone product. The Exchange accordingly amended its Fee Schedule to inform customers that it would cease offering connectivity to the GIF once it is no longer available.[6]

ICE has informed the Exchange that it ceased offering the GIF as a stand-alone product, making the references to the GIF obsolete. The operative date was announced through a customer notice. Accordingly, the Exchange proposes to remove ''ICE Data Global Index * '' and the corresponding asterisked note from the Fee Schedule.

In order to implement the proposed change, the Exchange proposes to make the following changes to the section of the Fee Schedule entitled ''Connectivity to Third Party Data Feeds'':

- In the first paragraph and in the table of Third Party Data Feeds, delete ''ICE Data Global Index * ''.
- Following the table of Third Party Data Feeds, delete the following text:

** ICE will cease to offer the GIF as a stand-alone product, which the Exchange has been informed by ICE is currently expected to occur before the end of 2020. The Exchange will announce the operative date through a customer notice. Any change fees that a User would otherwise incur as a result of the proposed change will be waived.*

(4) Proposal To Remove the Temporary Waiver of Hot Hands Fees

The Exchange proposes to remove the obsolete reference to the waiver of Hot Hands fees in light of the reopening of the data center in Mahwah, New Jersey (''Mahwah Data Center'' or ''MDC'').

In March 2020, ICE announced to each User that, starting on March 16, 2020, the MDC would be closed to third parties in response to COVID–19. The Exchange temporarily waived all Hot Hands fees from the date of the closing through the date of the reopening of the MDC, and added a note to the fees for the Hot Hands service stating as much.[7]

[6] *See* Securities Exchange Act Release No. 88990 (June 2, 2020), 85 FR 34778 (June 8, 2020) (SR–NYSECHX–2020–17).

[7] The Exchange first waived the Hot Hands Fee in a March 17, 2020 filing, and subsequently extended the waiver four times. *See* Securities Exchange Act Release Nos. 88400 (March 17, 2020),

Continued

The MDC reopened on October 1, 2020. The date of the reopening was announced through a customer notice. As a result of the reopening, the waiver of Hot Hands fees ceased, and the note became obsolete. The Exchange now proposes to remove the obsolete text.

In order to implement this proposed change, the Exchange proposes to make the following changes to the Fee Schedule:

• In the Types of Service table, remove the ''†'' symbol after ''Hot Hands Service *** ''.

• Following the Types of Service table, remove the following text:

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the reopening of the Mahwah, New Jersey data center. The date of the reopening will be announced through a customer notice.

(5) Proposal To Remove Obsolete Text About Transition Period for Suspended Services

The Exchange proposes to remove obsolete text regarding the transition period that expired on May 24, 2021 concerning the Exchange's provision of suspended services at no charge.

As background, on March 10, 2021, the Exchange filed with the Commission a proposed rule change for immediate effectiveness that amended the colocation services offered by the Exchange to provide Users the option to access the systems and data feeds of various additional third parties.[8] The proposed rule change became operative on April 9, 2021, and five Users subsequently contracted to receive the services that were added in the filing.

On May 7, 2021, the Commission suspended the filing and instituted proceedings to determine whether the proposed rule change should be approved or disapproved.[9] Such action suspended the Exchange's ability to offer access to Third Party Systems from Long Term Stock Exchange, Members Exchange, MIAX Emerald, MIAX PEARL Equities, Morgan Stanley, and TD Ameritrade, and to offer connectivity to Third Party Data Feeds from ICE Data Services—ICE TMC, Members Exchange, MIAX Emerald, and MIAX PEARL Equities (together, the ''Suspended Services'').

On May 12, 2021, the Commission approved for immediate effectiveness the Exchange's filing proposing to provide the Suspended Services to all Users, at no charge, for a period of 14 days (''Transition Period'') through May 24, 2021, to enable current Users to maintain their connectivity while establishing alternate connectivity.[10]

Given that the Transition Period has expired, the Exchange proposes to remove the obsolete text regarding this provision. To that end, the Exchange proposes to delete the following text:

Connectivity to Suspended Third Party Systems and Suspended Third Party Data Feeds

Connectivity to the Third Party Systems and Third Party Data Feeds listed below (''Suspended Services'') is available until May 24, 2021 (''Transition Period''). During the Transition Period, the Exchange will not charge any fees for the Suspended Services. At the conclusion of the Transition Period, any remaining customers of Suspended Services will have their Suspended Services terminated.

Suspended Third Party Systems
Long Term Stock Exchange (LTSE)
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities
Morgan Stanley
TD Ameritrade

Suspended Third Party Data Feeds
ICE Data Services—ICE TMC
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities

(6) Proposal To Remove LCN Access—1 Gb Circuit

The Exchange proposes to delete the service ''LCN Access—1 Gb Circuit'' from the list of available types of services. The number of 1 Gb LCN ports purchased by Users has steadily declined from 4 in 2017, to 2 in 2018, to 1 in 2021, to zero currently. The Exchange understands that this fall-off in demand for the 1 Gb LCN port is due to the fact that market data feeds continue to increase in bandwidth, such that Users prefer to purchase larger port sizes. Indeed, the last remaining User with a 1 Gb LCN port discontinued that port in June 2022 and has switched to a 10 Gb LCN port instead. The Exchange believes that there is no remaining User demand for the 1 Gb LCN port, and accordingly, the Exchange proposes to discontinue the service as obsolete.

Application and Impact of the Proposed Changes

The Exchange does not expect that the proposed changes would have any impact. The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users[11] equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that updating the names of existing Third Party Services and Third Party Data Feeds and removing obsolete text from the Fee Schedule would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Updating the names of the Third Party Services and Third Party Data Feeds at issue will enhance the clarity and transparency of the Fee Schedule and reduce potential customer confusion. Removing obsolete references to (i) the

85 FR 16434 (March 23, 2020) (SRNYSECHX–2020–07); 88522 (March 31, 2020), 85 FR 19191 (April 6, 2020) (SR–NYSECHX–2020–10); 88957 (May 27, 2020), 85 FR 33766 (June 2, 2020) (SR–NYSECHX–2020–15); 89176 (June 29, 2020), 85 FR 40377 (July 6, 2020) (SR–NYSECHX–2020–19); and 89654 (August 25, 2020), 85 FR 53879 (August 31, 2020) (SR–NYSECHX–2020–25).

[8] *See* Securities Exchange Act Release No. 91390 (March 23, 2021), 86 FR 16424 (March 29, 2021) (SR–NYSECHX–2021–04).

[9] *See* Securities Exchange Act Release No. 91790 (May 7, 2021) (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca-2021–15, SR–NYSECHX–2021–04, SR–NYSENAT–2021–05).

[10] *See* Securities Exchange Act Release No. 91862 (May 12, 2021) (SR–NYSECHX–2021–10).

[11] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* 84 FR 58778, *supra* note 4, at 58778 n.6. As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

GIF and its associated fee, (ii) the note regarding the Hot Hands service, and (iii) the availability of the Suspended Services would make it easier to read, understand, and administer the Fee Schedule, enhancing its clarity and transparency and alleviating possible customer confusion.

Similarly, the Exchange believes that discontinuing offering the 1 Gb LCN connection would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb LCN connection has declined in recent years and there are currently no Users that subscribe to the service. The Exchange does not expect demand to rebound given Users' overall preference for larger port sizes to accommodate larger market data feeds. Removing references to the fees for this obsolete service from the Price List would make the Price List easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would update obsolete product names, delete obsolete services, and remove obsolete text from the Fee Schedule, in order to enhance transparency and alleviate potential customer confusion.

The Exchange believes that updating the names of existing Third Party Systems and Third Party Data Feeds and removing obsolete text from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the names of the existing systems and data feeds at issue would be updated and clarified in the Fee Schedule for all Users; the obsolete 1 Gb LCN connection would be removed for all Users; and obsolete text regarding the GIF, the note to the Hot Hands service, and the availability of the Suspended Services would be removed from the Fee Schedule as to all Users.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services and product names.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSECHX–2022–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2022–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2022–17 and should be submitted on or before August 19, 2022.

[14] 15 U.S.C. 78f(b)(8).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16255 Filed 7–28–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95363; File No. SR–MRX–2022–10]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing of a Proposed Rule Change Relating to Complex Orders In Connection With a Technology Migration

July 25, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 18, 2022, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 3, Section 7, Types of Orders and Order and Quote Protocols; Options 3, Section 10, Priority of Quotes and Orders; Options 3, Section 13, Price Improvement Mechanisms for Crossing Transactions; Options 3, Section 14, Complex Orders; and Options 3, Section 16, Complex Risk Protections.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In connection with a technology migration to an enhanced Nasdaq, Inc. (''Nasdaq'') functionality which will result in higher performance, scalability, and more robust architecture, the Exchange intends to adopt certain trading functionality currently utilized at Nasdaq affiliate exchanges. Also, the Exchange intends to remove certain functionality. Specifically, the following sections would be amended: Options 3, Section 7, Types of Orders and Order and Quote Protocols, Options 3, Section 10, Priority of Quotes and Orders; Options 3, Section 13, Price Improvement Mechanisms for Crossing Transactions; Options 3, Section 14, Complex Orders; and Options 3, Section 16, Complex Risk Protections. Each change will be described below.

Legging Order

The Exchange proposes to amend Options 3, Section 7(k)(1) to add a provision which states that a Legging Order[3] will not be generated during a Posting Period, as described in detail below, in progress on the same side in the series pursuant to Options 3, Section 15 regarding Acceptable Trade Range (''ATR''). A Legging Order would not be generated because it would no longer be at the Exchange's displayed best bid or offer, therefore, generating a Legging Order during a Posting Period in progress, on the same side in the series, would lead to its immediate removal, making it superfluous to have been generated.

ATR is a risk protection, that sets dynamic boundaries within which quotes and orders may trade. It is designed to guard the System[4] from experiencing dramatic price swings by preventing the immediate execution of quotes and orders beyond the thresholds set by this risk protection. In a separate proposal, the Exchange proposes to amend MRX's ATR to adopt an iterative process wherein an order/quote that reaches its ATR boundary will be paused for a brief period of time to allow more liquidity to be collected, before the order/quote is automatically re-priced and a new ATR is calculated.[5]

Specifically, in MRX–2022–5P, the Exchange proposes to amend current Options 3, Section 15(a)(2)(A)(iii) to provide that if an order or quote reaches the outer limit of the ATR (''Threshold Price'') without being fully executed, it will be posted at the Threshold Price for a brief period, not to exceed one second (''Posting Period''), to allow the market to refresh and determine whether or not more liquidity will become available (on the Exchange or any other exchange if the order is designated as routable) within the posted price of the order or quote before moving on to a new Threshold Price.[6] Upon posting, either the current Threshold Price of the order/quote or an updated NBB for buy orders/quotes or the NBO for sell orders/quotes (whichever is higher for a buy order/quote or lower for a sell order/quote) would become the reference price for calculating a new ATR. If the order remains unexecuted, a new ATR will be calculated and the order will execute, route, or post up to the new Threshold Price. This process will repeat until either (1) the order/quote is executed, cancelled, or posted at its limit price or (2) the order/quote has been subject to a configurable number of instances of the ATR as determined by the Exchange (in which case it will be returned). During the proposed Posting Period, an order would be in flux and would potentially increase (decrease) past the price of any Legging Order generated on the bid (offer) as the order works its way through the book. Legging Orders are removed from the order book when they are no longer at the Exchange's displayed best bid or offer and, therefore, generating a Legging Order during a Posting Period in progress on the same side in the series would lead to its immediate removal. Accordingly, in the current proposal, the Exchange proposes to amend Options 3, Section 7(k)(1) to provide that a Legging Order would not be created during the Posting

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Legging Order is a limit order on the regular limit order book that represents one side of a Complex Options Order that is to buy or sell an equal quantity of two options series resting on the Exchange's Complex Order Book. *See* Options 3, Section 7(k).

[4] The term ''System'' means the electronic system operated by the Exchange that receives and disseminates quotes, executes orders and reports transactions. See MRX Options 1, Section 1(a)(49).

[5] MRX has separately filed to amend ATR within SR–MRX–2022–5P. Within SR–MRX–2022–5P, MRX proposes an iterative process for ATR wherein the Exchange will attempt to execute interest that exceeds the outer limit of the ATR for a brief period of time while that interest is automatically re-priced as described herein. Today, MRX would cancel, rather than re-price, any interest that exceeds the outer limit of the ATR.

[6] *See* SR–MRX–2022–5P.

Period in progress on the same side in the series. By way of example, assume that the ATR is set for $0.05, the MPV is $0.01 and the following quotations are posted on MRX and away markets:

AWAY EXCHANGE QUOTES

Exchange	Bid size	Bid price	Offer price	Offer size
ISE	10	$0.75	$0.90	10
AMEX	10	0.75	0.92	10
PHLX	10	0.75	0.94	10

MRX PRICE LEVELS

Exchange	Bid size	Bid price	Offer price	Offer size
MRX	10	$0.75	$0.90	10
MRX	10	0.75	0.95	10
MRX	10	0.75	1.00	10
MRX	10	0.75	1.05	10

MRX receives a routable order to buy 70 contracts at $1.10. The ATR is $0.05 and the reference price is the National Best Offer − $0.90. The ATR threshold is then $0.90 + $0.05 = $0.95. The order is allowed to execute up to and including $0.95. The System then pauses for a brief period not to exceed one second to allow the market (including other exchanges) to refresh and to determine whether additional liquidity will become available within the order's posted price. If additional liquidity becomes available on MRX or any away market, that liquidity will be accessed and executed.

- 10 contracts will be executed at $0.90 against MRX.
- 10 contracts will be executed at $0.90 against ISE.
- 10 contracts will be executed at $0.92 against AMEX.
- 10 contracts will be executed at $0.94 against PHLX.
- 10 contracts will be executed at $0.95 against MRX.
- Then, after executing at multiple price levels, the order is posted at $0.95 for a brief period not to exceed one second to determine whether additional liquidity will become available.
- During this pause, the MRX BBO for this option is 0.95×1.00.
- Assume the leg above with the Posting Period in process is Leg A of an A–B complex strategy.
- Leg B has a BBO of 0.85×0.88.
- Therefore, the cBBO[7] of this A–B complex strategy is 0.07×0.15.
  - (Leg A Bid 0.95 − Leg B Offer 0.88 = 0.07).
  - (Leg A Offer 1.00 − Leg B Bid 0.85 = 0.15).
- Also during the pause, a Complex Options Order to buy A–B arrives for net price of $0.11.
- The Complex Options Order could generate a Legging Order at $0.96 on the bid of Leg A, relying on the $0.85 bid to sell Leg B and achieve a net price $0.11, however the Legging Order is not generated because Leg A has an order on the bid side in an ATR Posting Period which will continue to move through the order book, and would ultimately lead to the immediate removal of the Legging Order once it is no longer at the Exchange's displayed best bid.
- A new ATR Threshold Price of $1.00 is determined (new reference price of $0.95 + $0.05 = $1.00).
- If, during the brief pause not to exceed 1 second, no liquidity becomes available within the order's posted price of $0.95, the System will then execute 10 contracts at $1.00.
- Then, after executing at multiple price levels, the order is posted at $1.00 for a brief period not to exceed one second to determine whether additional liquidity will become available.
- A new ATR Threshold Price of $1.05 is determined (new reference price of $1.00 + $0.05 = $1.05).
- During this time the MRX BBO would be $1.00 \times $1.05.
- If, during the brief pause not to exceed 1 second, no liquidity becomes available within the order's posted price of $1.00, the System will then execute 10 contracts at $1.05.

The Exchange believes from a System processing and user acceptance standpoint, the best practice is to wait for the ATR Posting Period to complete before attempting to generate a Legging Order on the same side in the series, as the time required to complete the ATR Posting Period is minimal. Nasdaq Phlx LLC's (''Phlx'') legging order rule in Options 3, Section 14(f)(iii)(C)(2) has the same restriction on generating legging orders during the ATR Posting Period as proposed to be added to MRX's Legging Order rule.[8]

Changes to the Single-Leg Price Improvement Mechanism for Crossing Transactions

The Price Improvement Mechanism (''PIM'') is a process by which an Electronic Access Member can provide price improvement opportunities for a transaction wherein the Electronic Access Member seeks to facilitate an order it represents as agent, and/or a transaction wherein the Electronic Access Member solicited interest to execute against an order it represents as agent (a ''Crossing Transaction''). The Exchange provides a PIM for single-leg[9] orders and for Complex Orders[10] and proposes to amend both single-leg and Complex PIM rules. The Exchange proposes to amend the single-leg PIM in Options 3, Section 13(d)(4) which currently provides,

> When a market order or marketable limit order on the opposite side of the market from the Agency Order ends the exposure period, it will participate in the execution of the Agency Order at the price that is mid-way between the best counter-side interest and the NBBO, so that both the market or marketable limit order and the Agency Order receive price improvement. Transactions will be rounded, when necessary, to the $.01 increment that favors the Agency Order.

Today, unrelated interest in the form of a market order or marketable limit order, on the opposite side of the market

[7] The ''cBBO'' represents the net price of a complex strategy comprised of the best bids and offers of the individual legs.

[8] Phlx Options 3, Section 14(f)(iii)(C)(2) provides that a Legging Order will not be created, ''. . .(ii) if there is . . . a Posting Period under Options 3, Section 15 regarding Acceptable Trade Range on the same side in progress in the series. . .''.

[9] *See* MRX Options 3, Section 13(a)–(d).

[10] *See* MRX Options 3, Section 13(e).

from an Agency Order,[11] may end an exposure period [12] within a single-leg PIM and participate in the execution of the Agency Order. The unrelated order would participate at the price that is mid-way between the best counter-side interest and the NBBO, so that both the market order or marketable limit order and the Agency Order receive price improvement.

First, the Exchange proposes to *not* permit unrelated marketable interest on the opposite side of the market from the Agency Order, which is received during a single-leg PIM, to early terminate a PIM. The Exchange proposes to amend MRX Options 3, Section 13(d)(4) to instead provide,

Unrelated market or marketable interest (against the MRX BBO) on the opposite side of the market from the Agency Order received during the exposure period will not cause the Crossing Transaction to end early and will execute against interest outside of the Crossing Transaction. If contracts remain from such unrelated order at the time the auction exposure period ends, they will be considered for participation in the order allocation process described in sub-paragraph (3).[13]

[11] An Agency Order is the part of a Crossing Transaction that an Electronic Access Member represents as agent. *See* MRX Options 3, Section 13(b).

[12] Upon entry of a Crossing Transaction into the PIM, a broadcast message that includes the series, price and size of the Agency Order, and whether it is to buy or sell, will be sent to all Members. The Exchange designates a time of no less than 100 milliseconds and no more than 1 second for Members to indicate the size and price at which they want to participate in the execution of the Agency Order (''Improvement Orders''). During the exposure period, Improvement Orders may not be canceled, but may be modified to (i) increase the size at the same price, or (ii) improve the price of the Improvement Order for any size up to the size of the Agency Order. During the exposure period, responses (including the Counter-Side Order, Improvement Orders, and any changes to either) submitted by Members shall not be visible to other auction participants. The exposure period will automatically terminate (i) at the end of the time period designated by the Exchange pursuant to Options 3, Section 13(c)(1) above, (ii) upon the receipt of a market or marketable limit order on the Exchange in the same series, or (iii) upon the receipt of a non-marketable limit order in the same series on the same side of the market as the Agency Order that would cause the price of the Crossing Transaction to be outside of the best bid or offer on the Exchange. *See* MRX Options 3, Section 13(c).

[13] Subparagraph (3) of Options 3, Section 13(d) describes the manner in which a Counter-Side Order would be allocated. The Counter Side Order is one part of a Crossing Transaction and represents the full size of the Agency Order. The Counter-Side Order may represent interest for the Member's own account, or interest the Member has solicited from one or more other parties, or a combination of both. *See* MRX Options 3, Section 13(b).

Today, Phlx [14] and Nasdaq BX, Inc. (''BX'') [15] similarly do not permit unrelated interest on the opposite side of the market from the Agency Order to early terminate their price improvement auctions. With this proposed change, the single-leg PIM exposure period would continue for the full period despite the receipt of unrelated marketable interest on the opposite side of the market from the Agency Order. Allowing the single-leg PIM to run its full course would provide an opportunity for additional price improvement to the Crossing Transaction. Further, the unrelated interest would participate in the single-leg PIM allocation with any residual contracts remaining after interacting with the order book pursuant to MRX Options 3, Section 13(d). The aforementioned residual contracts are contracts that remain available for execution after the unrelated order on the opposite side of market as the Agency Order, which was marketable with bids and offers on the same side of the market as the Agency Order, executed against bids and offers on the Exchange's order book.

Second, the Exchange also proposes to amend current MRX Options 3, Section 13(c)(5) which states,

The exposure period will automatically terminate (i) at the end of the time period designated by the Exchange pursuant to Options 3, Section 13(c)(1) above, (ii) upon the receipt of a market or marketable limit order on the Exchange in the same series, or (iii) upon the receipt of a non-marketable limit order in the same series on the same side of the market as the Agency Order that would cause the price of the Crossing Transaction to be outside of the best bid or offer on the Exchange.

Specifically, the Exchange proposes to remove ''(ii),'' which provides the exposure period will automatically terminate ''. . . (ii) upon the receipt of a market or marketable limit order on the Exchange in the same series . . .''. The Exchange notes that this sentence applies to the receipt of marketable orders both on the same side and opposite side of the Agency order. As described above, the Exchange proposes to *not* permit unrelated marketable interest on the opposite side of the market from the Agency Order, which is received during a single-leg PIM, to early terminate a PIM. Therefore, with respect to the opposite side of the Agency Order, the termination of the auction will no longer be possible with the proposed change to MRX Options 3, Section 13(d)(4). With respect to the same side of the Agency Order, today, an unrelated market or marketable limit order in the same series on the same side of the Agency Order would cause the PIM to early terminate as well. At this time the Exchange proposes to *not* permit an unrelated market or marketable limit order in the same series *on the same side* of the Agency Order to cause the PIM to early terminate. This proposed change will align the functionality of MRX's PIM to that of BX's PRISM and Phlx's PIXL,[16] which do not permit an unrelated market or marketable limit order in the same series on the same side of the Agency Order to cause the PRISM or PIXL to early terminate, unless the BBO improves beyond the price of the Crossing Transaction on the same side. The Exchange notes that a market or marketable limit order in the same series on the same side of the Agency Order cannot interact with a PIM auction. The market or marketable limit order may interact with the single-leg order book, and if there are residual contracts that remain from the market or marketable limit order in the same series on the same side of the Agency Order, they could rest on the order book and improve the BBO beyond the price of the Crossing Transaction which would cause early termination pursuant to proposed Options 3, Section 13(c)(5)(ii) as discussed below. In this instance, residual contracts are contracts

[14] Phlx Options 3, Section 13(b)(4) provides that an unrelated market or marketable Limit Order (against the PBBO) on the opposite side of the market from the PIXL Order received during the Auction will not cause the Auction to end early and will execute against interest outside of the Auction. *See* Securities Exchange Act Releases No. 79835 (January 18, 2017), 82 FR 8445 (January 25, 2017) (SR–Phlx–2016–119) (Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Amend the PIXL Price Improvement Auction in Phlx Rule 1080(n) and To Make Pilot Program Permanent) and 63027 (October 1, 2010), 75 FR 62160 (October 7, 2010) (SR–Phlx–2010–108) (''PIXL Approval Order''). The Commission noted in SR–Phlx–2016–119 that, ''In approving this feature on a pilot basis, the Commission found that 'allowing the PIXL auction to continue for the full auction period despite receipt of unrelated orders outside the Auction would allow the auction to run its full course and, in so doing, will provide a full opportunity for price improvement to the PIXL Order. Further, the unrelated order would be available to participate in the PIXL order allocation.' The Exchange does not believe that this provision has had a significant impact on either the unrelated order or the PIXL Auction process, either for simple or Complex PIXL Orders. The Exchange therefore has requested that the Commission approve this aspect of the Pilot on a permanent basis for both simple and Complex PIXL Orders.''

[15] BX Options 3, Section 13(ii)(D) provides that unrelated market or marketable interest (against the BX BBO) on the opposite side of the market from the PRISM Order received during the Auction will not cause the Auction to end early and will execute against interest outside of the Auction.

[16] *See* Options 3, Section 13 of BX's PRISM Rules and Phlx's PIXL Rules.

that remain available for execution after the unrelated order on the same side of market as the Agency Order, which was marketable with bids and offers on the opposite side of the market as the Agency Order, executed against bids and offers on the Exchange's order book. The Exchange believes that this outcome would allow for the single-leg PIM exposure period to continue for the full period despite the receipt of unrelated marketable interest on the same side of the market from the Agency Order, provided residual interest does not go on to rest on the order book, improving the BBO beyond the price of the Crossing Transaction. Allowing the single-leg PIM to run its full course (unless the BBO improves beyond the price of the Crossing Transaction on the same side), rather than early terminate, would provide an opportunity for price improvement to the Agency Order.

Third, the Exchange proposes to amend current MRX Options 3, Section 13(c)(iii) to align the rule text more closely with language in BX Options 3, Section 13(ii)(B)(2).[17] Specifically, the Exchange proposes to amend Options 3, Section 13(c)(5) to delete current ''iii'' and renumber as ''ii''. Proposed new Options 3, Section 13(c)(5)(ii) would state, ''The exposure period will automatically terminate . . . (ii) any time the Exchange best bid or offer improves beyond the price of the Crossing Transaction on the same side of the market as the Agency Order . . .'' The proposed rule is designed to align to BX's rule text to remove any ambiguity that a market or marketable limit order priced more aggressively than the Agency Order could ultimately rest on the order book, improving the BBO beyond the price of the Crossing Transaction and, therefore, cause the early termination of a PIM auction.

By way of example, assume: MRX 1.00 x 2.00 (10) and a second MRX Market Maker's quote is 1.00 x 2.10 (10). If a PIM auction starts with a buy at 1.50, and subsequently an order to buy for 20 @2.00 arrives, the incoming order would trade with the quote, and the remaining 10 contracts would rest on the order book. Thereafter, the MRX BBO would update to 2.00 x 2.10 and trigger the early termination of the single-leg PIM pursuant to Options 3, Section 13(c)(5)(iii), which is being renumbered to Options 3, Section 13(c)(5)(ii). Early terminating the single-leg PIM in this example is necessary because the price of the single-leg PIM is no longer at the top of book (best price) and would not have execution priority with respect to responses or unrelated interest that arrive. By early terminating the single-leg PIM, MRX allows responses to the single-leg PIM, which arrived prior to the time the Exchange's best bid and offer improved beyond the Crossing Transaction, to execute.

The Exchange believes the proposed rule text will provide greater clarity to the manner in which the System operates today with respect to early termination of single-leg PIMs when the BBO on the same side improves beyond the price of the Crossing Transaction. The proposed amendment to the rule text is not intended to amend the current System functionality, rather it is intended to make clear that a market or marketable limit order could ultimately rest on the order book with residual interest and improve the BBO on the same side as the Agency Order beyond the price of the Crossing Transaction and cause the single-leg PIM to early terminate.

Fourth, the Exchange proposes to add a new MRX Options 3, Section 13(c)(5)(iii) which states, ''. . . (iii) any time there is a trading halt on the Exchange in the affected series . . .''. This proposed rule text is not modifying how the System currently operates.[18] Today, a trading halt would cause a single-leg PIM to early terminate. Current MRX Options 3, Section 13(d)(5) notes such an early termination as a result of the aforementioned trading halt. Adding this circumstance to the list of events that would terminate the exposure period would make the list complete and add clarity to the rule. Furthermore, the Exchange notes that in a separate rule change, SR–MRX–2022–5P,[19] the Exchange is proposing to amend Options 3, Section 13(d)(5) to change the System behavior such that if a trading halt is initiated after an order is entered into the PIM, such auction will be automatically terminated with execution solely with the Counter-Side Order. Today, if a trading halt is initiated after an order is entered into the PIM, such auction will be automatically terminated without execution.[20]

Changes to the Complex PIM

In accordance with the proposed rule change regarding the early termination provisions of a single-leg PIM auction explained above, the Exchange also proposes to remove a paragraph related to Complex PIM in current MRX Options 3, Section 13(e)(4)(vi) which provides,

> A Complex Price Improvement Mechanism in a complex strategy may be ongoing at the same time as a Price Improvement Auction pursuant to this Rule or during an exposure period pursuant to Supplementary Material .02 to Options 5, Section 2 in a component leg(s) of such Complex Order. If a Complex Price Improvement Mechanism is early terminated pursuant to paragraph (iv) above, and the incoming Complex Order that causes the early termination in the complex strategy is also marketable against a component leg(s) of the complex strategy that is the subject of a concurrent ongoing Price Improvement Auction pursuant to this Rule or an exposure period pursuant to Supplementary Material .02 to Options 5, Section 2, then the concurrent Complex Price Improvement Mechanism and component leg auction(s) are processed in the following sequence: (1) the Complex Price Improvement Mechanism is early terminated; (2) the component leg auction(s) are early terminated and processed; and (3) legging of residual incoming Complex Order interest occurs, except with respect to Stock Option Orders and Stock Complex Orders.

Today, unrelated marketable interest may cause the early termination of a single-leg PIM, if a component leg of a Complex Order is marketable against the order book in the same series as the single-leg PIM. An example is provided below.

Example #1 (Complex PIM Early Termination Elimination—Opposite Side)[21]

Complex Order Strategy A–B
MM Quote Leg A 4.20 (100) × 4.50 (100)

[17] BX Options 3, Section 13(ii)(B) provides ''Conclusion of Auction. The PRISM Auction shall conclude at the earlier to occur of (1) through (3) below, with the PRISM Order executing pursuant to paragraph (C)(1) or (C)(2) below if it concludes pursuant to (2) or (3) of this paragraph. (1) The end of the Auction period; (2) For a PRISM Auction any time the BX BBO crosses the PRISM Order stop price on the same side of the market as the PRISM Order; (3) Any time there is a trading halt on the Exchange in the affected series.''

[18] MRX Options 3, Section 13(d)(5) currently states that, ''If a trading halt is initiated after an order is entered into the Price Improvement Mechanism, such auction will be automatically terminated without execution.'' Of note, the Exchange is proposing to amend MRX's PIM within a separate rule change, SR–MRX–2022–5P. Among other things, the Exchange proposes to amend the PIM functionality so that if a trading halt is initiated after an order is entered into the PIM, the auction will be automatically terminated with an execution. Specifically, SR–MRX–2022–5P proposes to renumber current MRX Options 3, Section 13(d) to Options 3, Section 13(d)(6) and proposes to state, ''If a trading halt is initiated after an order is entered into the Price Improvement Mechanism, such auction will be automatically terminated with execution solely with the Counter-Side Order.''

[19] MRX has separately filed to amend Options 3, Section 13(d)(5) within SR–MRX–2022–5P. SR–MRX–2022–5P amends, among other things, the rule text in Options 3, Section 13, except that it does not amend Options 3, Section 13(c)(5).

[20] *See* current MRX Options 3, Section 13(d)(5).

[21] Example 1 addresses an order on the opposite side of the Agency Order, although the same early termination would apply to an order on the same side of an Agency Order pursuant to MRX Options 3, Section 13(e)(4)(vi).

MM Quote Leg B 4.00 (100) × 4.10 (100)
cBBO 0.10 × 0.50
(Leg A Bid 4.20 − Leg B Offer 4.10 = 0.10)
(Leg A Offer 4.50 − Leg B Bid 4.00 = 0.50)
Complex PIM to Buy A–B 10 @0.20, with an election to automatically match to a net price of 0.10

Complex PIM Begins

Single-leg PIM Auction on Leg A to Buy 100 @ 4.25

Single-Leg PIM Begins

During both auction timers, an unrelated marketable Complex Order A–B to sell 50 @ a net price of 0.10 arrives (the individual legs of the marketable Complex Order would be selling A @ 4.20 and buying B @ 4.10).

Complex Order PIM is early terminated and trades 4 with the Counter-Side Order @ a net price of 0.10 and 6 with the unrelated Complex Order @ a net price of 0.15.

Today, the unrelated Complex Order would have legged-in after trading with the Complex PIM and caused the single-leg PIM to early terminate because one leg of the Complex Order was marketable against the Leg A bid of 4.20.

With the proposed amendment, the unrelated Complex Order will not cause the single-leg PIM to early terminate as a result of trading with an unrelated order on the opposite side in the same series. The unrelated marketable Complex Order will trade with the Complex PIM as well as the best bids and offers from the single-leg order book. In this case, the remaining quantity of the unrelated Complex Order would leg-in and trade with the single-leg quotes without impacting the single-leg PIM; the single-leg PIM auction timer would conclude after running its full course. Thereafter, if there are no responses to the single-leg PIM, the Agency Order would trade 100 @ 4.25 with the Counter-Side Order.

Today, if a Complex PIM is early terminated pursuant to MRX Options 3, Section 14(e)(4)(iv) [22] and the incoming Complex Order that causes the early termination in the complex strategy is also marketable against a component leg(s) of the complex strategy that is the subject of a concurrent ongoing single-leg PIM, or an exposure period pursuant to flash functionality as provided for in Supplementary Material .02 to Options 5, Section 2,[23] then the concurrent Complex PIM and component leg auction(s) are processed in accordance with MRX Options 3, Section 14(e)(4)(vi).

With this proposed change, a single-leg PIM will no longer early terminate as a result of the arrival of unrelated marketable interest on either the same or the opposite side of the market from the Agency Order. Because a single-leg PIM will no longer early terminate from the arrival of unrelated marketable interest on either the same or the opposite side of the market from the Agency Order, and because the flash functionality will no longer exist,[24] the Exchange proposes to delete MRX Options 3, Section 13(e)(4)(vi) in its entirety.

Additionally, the Exchange proposes to remove a related paragraph in current Supplementary Material .01(b)(iii) of MRX Options 3, Section 14 describing Complex Order Exposure, which states,

A Complex Order Exposure in a complex strategy may be ongoing in a complex strategy at the same time as a Price Improvement Auction pursuant to Options 3, Section 13 or during an exposure period pursuant to Supplementary Material .02 to Options 5, Section 2 in a component leg(s) of such complex strategy. If a Complex Order Exposure is early terminated pursuant to paragraph (ii) above, and the incoming Complex Order that causes the early termination in the complex strategy is also marketable against a component leg(s) of the complex strategy that is the subject of a concurrent ongoing Price Improvement Auction pursuant to Options 3, Section 13 or an exposure period pursuant to Supplementary Material .02 to Options 5, Section 2, then the concurrent Complex Order and component leg auction(s) are processed in the following sequence: (1) the Complex Order exposure is early terminated; (2) the component leg auction(s), which are early terminated and processed; and (3) legging of residual incoming Complex Order interest occurs.

Today, unrelated marketable interest may cause the early termination of a single-leg PIM, therefore, when a Complex Order legs into the single-leg order book, it may cause the early termination of a single-leg PIM if that leg was on either the same or the opposite side of the market from the single-leg PIM. An example is provided below.

Example # 2 (Complex Exposure Early Termination Elimination—Opposite Side) [25]
Complex Order Strategy A–B
MM Quote Leg A 4.20 (100) × 4.50 (100)
MM Quote Leg B 4.00 (100) × 4.10 (100)
cBBO 0.10 × 0.50
(Leg A Bid 4.20 − Leg B Offer 4.10 = 0.10)
(Leg A Offer 4.50 − Leg B Bid 4.00 = 0.50)
Complex Order in A–B Strategy marked for Complex Order Exposure to buy 10 @ 0.20

Complex Order Exposure Auction Begins

Single-leg PIM Auction on Leg A to Buy 100 @ 4.25
Single-Leg PIM Begins

During both auction timers, unrelated marketable Complex Order A–B Sell 50 @ 0.10 arrives.

Complex Order Exposure is early terminated and the exposed order to buy A–B 10 @ 0.20 and trades with the unrelated Complex Order 10 @ net price of 0.10.

Today, the unrelated marketable Complex Order would have legged-in after trading with the Complex Order Exposure and caused the single-leg PIM to early terminate because one leg of the marketable Complex Order on the opposite side was marketable against the Leg A bid of 4.20.

With the proposed amendment, the unrelated marketable Complex Order will not cause the single-leg PIM on the opposite side in the same series to early terminate as a result of the component leg of the Complex Order being marketable against the bid in the same series as the single-leg PIM. The unrelated marketable Complex Order will trade with the Complex Order Exposure order as well as the best bids and offers from the single-leg order book. In this case, the remaining quantity would leg-in and trade with the single-leg quotes without impacting the single-leg PIM; the auction timer would conclude after running its full course. Thereafter, the Crossing Transaction would trade 100 @ 4.25 Agency Order with the Counter-Side Order.

Today, when a Complex Order Exposure early terminates, as a result of the arrival of unrelated marketable Complex Order interest that trades against the exposed Complex Order and the best bids and offers on the single-leg order book (as described in Supplementary Material .01(b)(ii) of MRX Options 3, Section 14), the component legs of the unrelated marketable Complex Order on either the same or the opposite side of the single-leg PIM may leg-in and cause early termination of the single-leg PIM. Thereafter, the component leg auction(s) would be processed pursuant to

[22] MRX Options 3, Section 14(e)(4)(iv) provides, ''The exposure period will automatically terminate (A) at the end of the time period designated by the Exchange pursuant to subparagraph (4)(i) above, (B) upon the receipt of a Complex Order in the same complex strategy on either side of the market that is marketable against the Complex Order Book or bids and offers for the individual legs, or (C) upon the receipt of a non-marketable Complex Order in the same complex strategy on the same side of the market as the Agency Complex Order that would cause the execution of the Agency Complex Order to be outside of the best bid or offer on the Complex Order Book.''

[23] Pursuant to Supplementary Material .02 to ISE Options 5, Section 2, ISE permits certain orders to first be exposed at the NBBO to all Members for execution at the National Best Bid or Offer (''NBBO'') before the order would be routed to another market for execution (''flash functionality''). MRX Options 5 Rules are incorporated by reference to ISE Options 5 Rules.

[24] MRX filed a rule change to eliminate its flash functionality. *See* Securities Exchange Act Release No. 94897 (May 12, 2022), 87 FR 30294 (May 18, 2022) (SR–ISE–2022–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Routing Functionality in Connection With a Technology Migration). MRX's rule regarding flash functionality at Supplementary Material .02 to Options 5, Section 2 is incorporated by reference to Nasdaq ISE, LLC Options 5 rules. Therefore, eliminating the flash functionality from ISE Options 5 rules also eliminates the flash functionality from MRX's Options 5 rules.

[25] Example 2 addresses an order on the opposite side of the Agency Order, although the same early termination would apply to an order on the same side of the Agency Order pursuant to Supplementary Material .01(b)(iii) of MRX Options 3, Section 14.

Supplementary Material .01(b)(iii) of MRX Options 3, Section 14. With this proposed change to MRX Options 3, Section 13(d)(4), a single-leg PIM will no longer early terminate from the arrival of unrelated marketable interest on either the same or opposite side of the market from the Agency Order. Therefore, because a single-leg PIM will no longer early terminate from the arrival of unrelated marketable interest on either the same or opposite side of the market from the Agency Order, and because the flash functionality will no longer exist,[26] the early termination provisions addressed in Supplementary Material .01(b)(iii) of MRX Options 3, Section 14 will no longer arise, accordingly, the Exchange proposes to delete Supplementary Material .01(b)(iii) of MRX Options 3, Section 14 in its entirety.

Complex Orders Delayed Functionality

The Exchange proposes to delay the implementation of certain functionality in connection with the technology migration. Specifically, Stock-Option Strategies,[27] Stock-Complex Strategies,[28] Complex QCC with Stock Orders,[29] and QCC with Stock Orders,[30] as defined in MRX Options 3, Sections 14(a)(2) and (3) and (b)(15) and Options 3, Section 7(t), respectively, and Trade Value Allowance,[31] as defined in Supplementary Material .03 of MRX Options 3, Section 14, would not be available for symbols that migrated to the platform (''Delayed Functionalities''). Today, these Delayed Functionalities are available to Members.

The Delayed Functionalities would not be available for symbols that migrated to the platform and thereafter, until such time as the Exchange recommenced their availability by announcing a date in an Options Trader Alert, which date would be prior to one year from the start of the migration of the symbols to the platform. The Exchange is staging the migration to provide maximum benefit to its Members while also ensuring a successful rollout. The Delayed Functionalities will provide the Exchange additional time to code, test and implement this functionality on the enhanced platform.

Other Complex Order Amendments

Opening Only Complex Order

Currently, MRX Options 3, Section 14(b)(10) states, ''An Opening Only Complex Order is a Limit Order that may be entered for execution during the Complex Opening Process described in Supplementary Material .04 to Options 3, Section 14. Any portion of the order that is not executed during the Complex Opening Process is cancelled.'' The Exchange proposes to amend MRX Options 3, Section 14(b)(10) to remove the word ''Limit'' within the description of the Opening Only Complex Order to allow Opening Only Complex Orders to be submitted as Market Orders or Limit Orders. This amendment is consistent with current System operations. The Exchange believes that both Market and Limit Orders should be permitted in the Complex Opening Process.[32] Market Orders are typically the most aggressively priced orders, while Limit Orders have a limit price contingency that Market Orders do not have. Allowing both of these order types to participate in the Complex Opening Process allows greater liquidity to be present to determine the Opening Price.[33] All Members may enter both Market Orders and Limit Orders during the Complex Opening Process, as well as intra-day.

Complex QCC With Stock Orders

The Exchange proposes to correct a non-substantive citation with MRX Options 3, Section 14(b)(15) related to Complex QCC with Stock Orders. The current citation to MRX Options 3, Section 12(e) within the description of this order type is incorrect. The citation should be to MRX Options 3, Section 12(f). Correcting this cross reference will clarify the description of the order type.

Complex Preferenced Orders

The Exchange proposes to add ''Complex Preferenced Orders'' to the list of Complex Order Types in Options 3, Section 14(b). This proposal describes how Complex Preferenced Orders will work. MRX Options 2, Section 10 currently describes Preferenced Orders which may be Complex Preferenced Orders.[34] To complete the list of Complex Order types, the Exchange proposes to state in MRX Options 3, Section 14(b)(19) that,

[a] Complex Preferenced Order is a Complex Order for which an Electronic Access Member has designated a Preferred Market Maker as described in Options 2, Section 10. The component leg(s) of a Complex Order with a Preferenced Order instruction may allocate pursuant to Options 3, Section 10(c)(1)(C) when the Complex Preferenced Order legs into the single-leg market provided that the Preferred Market Maker is

[26] *Id.* [sic]

[27] A Stock-Option Strategy is the purchase or sale of a stated number of units of an underlying stock or a security convertible into the underlying stock (''convertible security'') coupled with the purchase or sale of options contract(s) on the opposite side of the market representing either (A) the same number of units of the underlying stock or convertible security, or (B) the number of units of the underlying stock necessary to create a delta neutral position, but in no case in a ratio greater than eight-to-one (8.00), where the ratio represents the total number of units of the underlying stock or convertible security in the option leg to the total number of units of the underlying stock or convertible security in the stock leg. *See* MRX Options 3, Section 14(a)(2).

[28] A Stock-Complex Strategy is the purchase or sale of a stated number of units of an underlying stock or a security convertible into the underlying stock (''convertible security'') coupled with the purchase or sale of a Complex Options Strategy on the opposite side of the market representing either (A) the same number of units of the underlying stock or convertible security, or (B) the number of units of the underlying stock necessary to create a delta neutral position, but in no case in a ratio greater than eight-to-one (8.00), where the ratio represents the total number of units of the underlying stock or convertible security in the option legs to the total number of units of the underlying stock or convertible security in the stock leg. Only those Stock-Complex Strategies with no more than the applicable number of legs, as determined by the Exchange on a class-by-class basis, are eligible for processing. *See* MRX Options 3, Section 14(a)(3).

[29] A Complex QCC with Stock Order is a Qualified Contingent Cross Complex Order, as defined in subparagraph (b)(6) of Options 3, Section 14, entered with a stock component to be communicated to a designated broker-dealer for execution pursuant to MRX Options 3, Section 12(f).

[30] A QCC with Stock Order is a Qualified Contingent Cross Order, as defined in Options 3, Section 7(j), entered with a stock component to be communicated to a designated broker-dealer for execution pursuant to Options 3, Section 12(c). *See* Options 3, Section 7(t).

[31] Trade Value Allowance permits Stock-Option Strategies and Stock-Complex Strategies at valid increments Options 3, Section 14(c)(1), Stock-Option Strategies and Stock-Complex Strategies to trade outside of their expected notional trade value by a specified amount, in order to facilitate the execution of the stock leg and options leg(s). The Trade Value Allowance is the percentage difference between the expected notional value of a trade and the actual notional value of the trade. The amount of Trade Value Allowance permitted may be determined by the Member, or a default value determined by the Exchange and announced to Members; provided that any amount of Trade Value Allowance is permitted in mechanisms pursuant to Options 3, Sections 11 and 13 when auction orders do not trade solely with their contra-side order. *See* Supplementary Material .03 of MRX Options 3, Section 14.

[32] The Complex Opening Process is described in Supplementary Material .04 of MRX Options 3, Section 14.

[33] The Opening Price is described in MRX Options 3, Section 14(a)(2).

[34] MRX Options 2, Section 10 provides, ''Preferenced Orders. An Electronic Access Member may designate a ''Preferred Market Maker'' on orders it enters into the System (''Preferenced Orders''). (1) A Preferred Market Maker may be the Primary Market Maker appointed to the options class or any Competitive Market Maker appointed to the options class. (2) If the Preferred Market Maker is not quoting at a price equal to the NBBO at the time the Preferenced Order is received, the allocation procedure described in Options 3, Section 10(c)(1)(C) shall not be applied to the execution of the Preferenced Order. (3) If the Preferred Market Maker is quoting at the NBBO at the time the Preferenced Order is received, the allocation procedure described in Options 3, Section 10(c)(1)(C) shall be applied to the execution of the Preferenced Order.''

quoting at the NBBO for a component leg(s) of the Complex Preferenced Order at the time the Complex Preferenced Order is received. A Preferred Market Maker will not receive an allocation pursuant to Options 3, Section 10(c)(1)(C) for a component leg(s) of a Complex Preferenced Order if the Preferred Market Maker is not quoting at the NBBO for that leg at the time the Complex Preferenced Order is received.

Allocation of a leg(s) of a Complex Preferenced Order, pursuant to MRX Options 3, Section 10, would occur when a leg(s) of a Complex Order trades synthetically with the Preferred Market Maker's [35] quote that was at the NBBO on the single-leg order book in accordance with MRX Options 3, Section 10. A Preferred Market Maker must be quoting at the NBBO for a component leg(s) of the Complex Preferenced Order at the time the Complex Preferenced Order is received. As is the case for single-leg orders, a Preferred Market Maker will not receive an allocation pursuant to Options 3, Section 10(c)(1)(C) for a component leg(s) of a Complex Preferenced Order if the Preferred Market Maker is not quoting at the NBBO for that leg at the time the Complex Preferenced Order is received.

With respect to orders which leg into the single-leg order book, MRX Options 3, Section 14(c) states that, ''Except as otherwise provided in this Rule, complex strategies shall be subject to all other Exchange Rules that pertain to orders and quotes generally.'' Additionally, the Exchange notes that orders that execute against interest on the single-leg order book, including the options leg of Complex Options Strategies are subject to the provisions of MRX Options 3, Section 5 which, among other things, describes the NBBO Price Protection and Trade-Through Compliance and Locked or Crossed Markets.

Further, Supplementary Material .01 to Options 9, Section 1 provides,

[i]t will be a violation of this Rule for a Member to have a relationship with a third party regarding the disclosure of agency orders. Specifically, a Member may not disclose to a third party information regarding agency orders represented by the Member prior to entering such orders into the System to allow such third party to attempt to execute against the Member's agency orders. A Member's disclosing information regarding agency orders prior to the execution of such orders on the Exchange would provide an inappropriate informational advantage to the third party in violation of this Rule. For purposes of this paragraph .01, a third party includes any other person or entity, including affiliates of the Member. Nothing in this paragraph is intended to prohibit a Member from soliciting interest to execute against an order it represents as agent (a ''solicited order''), the execution of which is governed by Options 3, Section 22(e) and paragraph .02 of Supplementary Material to Options 3, Section 22.

This rule prohibits a Member from notifying a Preferred Market Maker of an intention to submit a Complex Preferenced Order so that the Preferred Market Maker could change its quotation to match the NBBO immediately prior to submission of the Complex Preferenced Order, and then fade its quote. The Exchange represents that it proactively conducts surveillance for, and enforces against, violations of Supplementary Material .01 to Options 9, Section 1.

The Exchange's proposal to add ''Complex Preferenced Orders'' to the list of Complex Order Types in MRX Options 3, Section 14(b) will continue to encourage Preferred Market Makers to quote aggressively in an effort to execute against the Complex Preferenced Order. Preferred Marker Makers are not able to ascertain if a particular order is a Complex Preferenced Order. The Exchange believes the proposal will encourage Market Makers to quote tighter and add a greater amount of liquidity on MRX in an attempt to interact with Complex Preferenced Orders that are sent to the Exchange. This order flow will benefit all market participants on the Exchange because any MRX Member may interact with that order flow.

The addition of Complex Preferenced Orders to the list of order types in MRX Options 3, Section 14(b) will make clear to Members the availability of Complex Preferenced Orders. Both Phlx [36] and MIAX [37] have a similar order type.

Options 3, Section 14(c)(2) and MRX Supplementary Material .02 to Options 3, Section 14

The Exchange proposes a non-substantive amendment in MRX Options 3, Section 14(c)(2) to amend an incorrect reference to ''ISE''. The reference should be to ''MRX''. Also, the Exchange proposes to make a non-substantive technical correction in Supplementary Material .02 of MRX Options 3, Section 14 to make a grammatical amendment to change the word ''which'' to ''whom''.

Complex Opening Price Determination

The Exchange proposes to amend the citation within Supplementary Material .05(d)(2) to Options 3, Section 14 which states, ''*Potential Opening Price.* The System will calculate the Potential Opening Price by identifying the price(s) at which the maximum number of contracts can trade (''maximum quantity criterion'') taking into consideration all eligible interest pursuant to Supplementary Material .06(b) to this Rule.'' The citation to Supplementary Material .06(b), related to Uncrossing is incorrect. The citation should be to Supplementary Material .05(b), related to Complex Opening Price Determination. The citation is referring is [sic] to eligible interest during the Complex Opening Price Determination.

The Exchange proposes to amend the Complex Opening Price Determination in Supplementary Material .05(d)(3) to Options 3, Section 14 to allow for additional contracts to be included in the Potential Opening Price calculation leading to better price discovery and more contracts executing as part of the Complex Opening Price Determination process.

With this proposal, when the interest does not match the size and there is more than one Potential Opening Price at which the interest may execute, the Exchange would calculate a Potential Opening Price using the mid-point of the highest (lowest) executable offer (bid) price and the next available executable offer (bid) price rounded, if necessary, down (up) to the closest minimum trading increment. As a result, more options contracts are likely to be executed at better prices than under the current rule. Example number 3 below demonstrates this behavior. This behavior differs from current rules in that, today, the Exchange would calculate the Potential Opening Price as the highest (lowest) executable bid (offer) when there would be contracts left unexecuted on the bid (offer) side of the complex market.

[35] Preferred Market Maker may be the Primary Market Maker appointed to the options class or any Competitive Market Maker appointed to the options class. *See* MRX Options 2, Section 10(a)(1).

[36] *See* Phlx Options 3, Section 14(b)(v) which specifies that a Directed Order may be submitted as a Complex Order. *See also* Phlx Options 3, Section 7(b)(11) which describes a Directed Order. Phlx's Options 2, Section 10 Directed Order rule is similar to MRX's Options 2, Section 10 Preferenced Order rule.

[37] A ''Directed Order'' is an order entered into the System by an Electronic Exchange Member with a designation for a Lead Market Maker (referred to as a ''Directed Lead Market Maker''). Only Priority Customer Orders will be eligible to be entered into the System as a Directed Order by an Electronic Exchange Member. *See* MIAX Rule 100. *See also* MIAX Rule 514(h) which describes allocation. Today, MIAX permits Directed Orders to be submitted as a New Order—Multileg. *See https://www.miaxoptions.com/sites/default/files/page-files/FIX%20Order%20Interface_FOI_v2.5a_re.pdf.* Pursuant to MIAX's specifications, ''AllocAccount (Tag 79) is defined as MIAX assigned directed firm code of the designated participant for directed order flow.''

Further, the proposed amendment will allow Market Complex Orders to participate in the Opening Price Determination process in a broader capacity than the rule allows for today. Today, if there are only Market Complex Orders on both sides of the market, or if there are Market Complex Orders on the bid (offer) side of the market for greater than the total size of Complex Orders on the offer (bid) side of the market, then MRX will not trade in the Complex Opening Price Determination process and would instead open pursuant to an Uncrossing as provide [sic] for in Supplementary Material .06(b) of MRX Options 3, Section 14. With the proposed amendment Market Complex Orders will be included in the Complex Opening Price Determination process in both situations described above, leading to more contracts being able to trade in the Complex Opening Price Determination with better price discovery. Example 5 below illustrates this point.

Finally, the proposed amendment considers the Boundary Price earlier in the Complex Opening Process. Today, the rule seeks to satisfy the maximum quantity criterion first and then consider Boundary Prices. With the proposed change, the Exchange will consider the Boundary Price while determining the Potential Opening Price, thereby enabling as many contracts as possible to trade sooner, which reduces risk for market participants awaiting executions. With this proposal, the Complex Opening Process considers the Boundary Price earlier in the process and the Boundary Price becomes the limit price for Market Complex Orders. This proposal should maximize the number of contracts executed, to the benefit of those Members participating in that complex strategy.

Current Supplementary Material .05 of MRX Options 3, Section 14 describes how Complex Orders arrive at an Opening Price. Specifically, Supplementary .05(b) of MRX Options 3, Section 14 describes the interest that is eligible within the Complex Opening Price Determination. The rule text provides that the System would calculate Boundary Prices [38] at or within which Complex Orders may be executed during the Complex Opening Price Determination.[39] Current Supplementary Material .05(d)(2) of MRX Options 3, Section 14 provides,

''The System will calculate the Potential Opening Price [40] by identifying the price(s) at which the maximum number of contracts can trade (''maximum quantity criterion'') taking into consideration all eligible interest pursuant to Supplementary Material .06(b) to this Rule.'' [41] The System takes into consideration all Complex Orders, identifies the price at which the maximum number of contracts can trade, and calculates the Potential Opening Price as described in Supplementary Material .05(d)(2) of MRX Options 3, Section 14. Supplementary Material .05(d)(3) of MRX Options 3, Section 14 further describes the way the System handles more than one Potential Opening Price. Current Supplementary Material .05(d)(3) of MRX Options 3, Section 14 states,

When two or more Potential Opening Prices would satisfy the maximum quantity criterion: (A) without leaving unexecuted contracts on the bid or offer side of the market of Complex Orders to be traded at those prices, the System takes the highest and lowest of those prices and takes the mid-point; provided that (1) if the highest and/or lowest price described above is through the price of a bid or offer that is priced to not allocate in the Complex Opening Price Determination, the highest and/or lowest price will be rounded to the price of such bid or offer that is priced to not allocate before taking the mid-point, and (2) if the midpoint is not expressed as a permitted minimum trading increment, it will be rounded down to the nearest permissible minimum trading increment; or (B) leaving unexecuted contracts on the bid (offer) side of the market of Complex Orders to be traded at those prices, the Potential Opening Price is the highest (lowest) executable bid (offer) price. Notwithstanding the foregoing: (C) if there are Market Complex Orders on the bid (offer) side of the market that would equal the full quantity of Complex Orders on offer (bid) side of the market, the limit price of the highest (lowest) priced Limit Complex Order is the Potential Opening Price; and (D) if there are only Market Complex Orders on both sides of the market, or if there are Market Complex Orders on the bid (offer) side of the market for greater than the total size of Complex Orders on the offer (bid) side of the market, there will be no trade in the Complex Opening Price Determination and the complex strategy will open pursuant to the Complex Uncrossing Process described in Supplementary Material .06(b) to this Rule.

At this time, the Exchange proposes to amend the System handling within the Complex Opening Process by replacing Supplementary Material .05(d)(3) of MRX Options 3, Section 14 with the following proposed rule text,

Opening Price Determination. When interest crosses and does not match in size, the System will calculate the Potential Opening Price based on the highest (lowest) executable offer (bid) price when the larger sized interest is offering (bidding), provided, however, that if there is more than one price at which the interest may execute, the Potential Opening Price when the larger sized interest is offering (bidding) shall be the mid-point of the highest (lowest) executable offer (bid) price and the next available executable offer (bid) price rounded, if necessary, down (up) to the closest minimum trading increment; or

When interest crosses and is equal in size, the System will calculate the Potential Opening Price based on the mid-point of lowest executable bid price and the highest executable offer price, rounded, if necessary, up to the closest minimum trading increment.

(A) Executable bids/offers include any interest which could be executed at the Potential Opening Price without trading through residual interest or the Boundary Price or without trading at the Boundary Price where there is Priority Customer interest at the best bid or offer for any leg, consistent with paragraph Options 3, Section 14(c)(2).

(B) Executable bids/offers will be bounded by the Boundary Price on the contra-side of the interest, for determination of the Potential Opening Price described above.

This proposed new Complex Opening Process seeks to maximize the interest which is traded during the Complex Opening Price Determination process and deliver a rational price for the available interest at the opening. The Complex Opening Price Determination process maximizes the number of contracts executed during the Complex Opening Process and ensures that residual contracts of partially executed orders or quotes are at a price equal to or inferior to the Opening Price. In other words, the logic ensures there is no remaining unexecuted interest available at a price which crosses the Opening Price. If multiple prices exist that ensure that there is no remaining unexecuted interest available through such price(s), the opening logic selects the mid-point of such price points. Below are some examples.

Example # 3 (More Than One Potential Opening Price—Mid-Point of Larger-Sized Interest)

''*if there is more than one price at which the interest may execute, the Potential Opening Price when the larger sized interest is offering (bidding) is the mid-point of the highest (lowest) executable offer (bid) price and the next available executable offer (bid) price*

[38] The Boundary Price is described in Supplementary Material .05(d)(1) of MRX Options 3, Section 14(a)(1).

[39] *See* Supplementary Material .05(d)(1) of MRX Options 3, Section 14.

[40] The Potential Opening Price is described in Supplementary Material .05(d)(2) of MRX Options 3, Section 14.

[41] The Exchange proposes to amend the citation within Supplementary Material .05(d)(2) to Options 3, Section 14 within this proposal. The citation to Supplementary Material .06(b), related to Uncrossing, should be to Supplementary Material .05(b), related to Complex Opening Price Determination. Specifically, the reference is to Eligible Interest during the Complex Opening Price Determination.

rounded, if necessary, down (up) to the closest minimum trading increment''

Assume

Complex Order Strategy: A+B strategy
Quote for Leg A @ 1.75 × 1.95
Quote for Leg B @ 1.75 × 1.95
Boundary Price = 3.50 (10) − 3.90 (10)
(Leg A Bid 1.75 + Leg B Bid 1.75 = 3.50)
(Leg A Offer 1.95 + Leg B Offer 1.95 = 3.90)
Complex Order #1: Buy 20 for $3.79
Complex Order #2: Buy 20 at $3.73
Complex Order #3: Sell 20 at $3.60

With the proposed amendment, Opening Price would be for 20 strategies at a price of $3.76. The execution price of $3.76 is derived from the mid-point of the lowest executable bid price of $3.73 and the next available executable bid price of $3.79. In this example, 20 strategies can be opened at multiple price points ranging from $3.73 up to $3.79. None of these Potential Opening Prices would cause the unexecuted $3.73 buy order to be available at a price which crosses the Opening Price, therefore, the System opens at the mid-point of such prices, $3.76.

Today, with this same example, the Opening Price would be 3.79, the highest executable bid price, which provides the offer side with all price improvement. With the proposed amendment, the Opening Price seeks to distribute to the extent possible price improvement to both the bid and offer side of the transaction.

Example # 4 (Mid-Point When Interest is Equal In Size)

''*Provided such crossing interest is equal in size, the System will calculate the Potential Opening Price based on the mid-point of lowest executable bid price and the highest executable offer price, rounded, if necessary, up to the closest minimum trading increment*''

Complex Order Strategy: A+B strategy
Quote for Leg A @ 1.75 × 1.95 each
Quote for Leg B @ 1.75 × 1.95 each
Boundary Price= 3.50 (10) − 3.90 (10)
(Leg A Bid 1.75 + Leg B Bid 1.75 = 3.50)
(Leg A Offer 1.95 + Leg B Offer 1.95 = 3.90)
Complex Order #1: Buy 10 for $3.78
Complex Order #2: Buy 20 for $3.74
Complex Order #3: Buy 10 at $3.71
Complex Order #4: Sell 20 at $3.64
Complex Order #5: Sell 20 at $3.66

With the proposed amendment, the Opening Price will be for 40 strategies at a price of $3.69. The execution price of $3.69 is derived from the mid-point of the lowest executable bid price of $3.71 and the highest executable offer price of $3.66, rounded up to the closest minimum trading increment. Today, rounding would be down and with this proposal the rounding would be up. If the example were changed slightly such that Complex Order #4 and Complex Order #5 were Market Complex Orders rather than Limit Orders, the Opening Price for the 40 strategies would be $3.61, which is derived from the mid-point of the lowest executable bid price of $3.71 and the highest executable offer of $3.50 (which is the Boundary Price of the sell Market Complex Orders), rounded up to the closest minimum trading increment.

The Exchange notes that executable bids/offers include any interest that could be executed at the net price without trading through residual interest or the Boundary Price, or without trading at the Boundary Price where there is Priority Customer interest at the best bid or offer for any leg, consistent with current MRX Options 3, Section 14(c)(2).[42] Further, executable bids/offers would be bounded to the Boundary Price on the contra-side of the interest, for determination of the Opening Price described above when crossing interest is different in size and when crossing interest is equal in size.

The amendment will benefit Members by smoothing the way for the complex strategy to open with Market Complex Orders. Today, Market Complex Orders participate in the Complex Opening Process in a limited capacity as explained above. By permitting Market Complex Orders to participate in the Complex Opening Price Determination process in more situations, the Exchange can provide more opportunity for Complex Orders to trade in the Opening Process without having to go to the Uncrossing process. Market conditions can change between the Complex Opening Price Determination process and the Uncrossing process, which can lead to missed opportunities for execution. The proposed rule would have the Boundary Price assign limits to the Opening Price and therefore permit Market Complex Orders to participate in the Complex Opening Process to the extent that they are within the Boundary Prices. With this change, MRX would permit a complex strategy to calculate an Opening Price utilizing a greater number of Market Complex Orders, which benefits the Opening Process by taking into account these more aggressively priced orders[43] while also bringing more liquidity into the Opening Price calculation.

Example # 5 (Market Complex Orders Trading in Opening Price Determination)

''*Provided interest crosses and does not match in size, the System will calculate the Potential Opening Price based on the highest (lowest) executable offer (bid) price when the larger sized interest is offering (bidding)*''

As referenced above,

Assume

Complex Order Strategy: A+B strategy
Quote for Leg A @ 1.75 × 2.00
Quote for Leg B @ 1.75 × 2.00
Boundary Price = 3.50 (10) − 4.00 (10)
(Leg A Bid 1.75 + Leg B Bid 1.75 = 3.50)
(Leg A Offer 2.00 + Leg B Offer 2.00 = 4.00)
Market Complex Order #1: Buy 30
Complex Order #2: Sell 20 at $3.95
After Complex Opening Price Determination process, but before Uncrossing
ABBO for Leg A updates: 1.85 x 1.90
ABBO for Leg B updates 1.85 x 1.90
cNBBO: 3.70 x 3.80
(ABBO Leg A Bid 1.85 + Leg B Bid 1.85 = 3.70)
(ABBO Leg A Offer 1.90 + Leg B Offer 1.90 = 3.80)

With the proposed amendment the Market Complex Order can be considered in the Complex Opening Price Determination process and therefore is able to trade at the Opening Price of $4.00 for 20 strategies with Complex Order #2 and also able to trade 10 strategies at a net price $4.00 with the individual legs at the best bids and offers before the ABBO updates, leaving no place for this complex strategy to trade. The Opening Price in this example is determined as the lowest executable bid because the bid side is the larger sized interest, which is limited by the Boundary Price on the offer side at 4.00.

Today, Market Complex Orders with a larger quantity than the quantity of interest on the contra side of the market do not participate in the Complex Opening Price Determination and can only execute during the Uncrossing pursuant to Supplementary Material .05(d)(6) of MRX Options 3, Section 14. In the example above, the ABBO of each leg updates after the Complex Opening Price Determination process and restricts the Market Complex Order and Complex Limit Order from trading in the Uncrossing because they cannot match at a price that would be within the Price Limits for Complex Orders

[42] MRX Options 3, Section 14(c)(2) provides, ''Complex strategies will not be executed at prices inferior to the best net price achievable from the best ISE bids and offers for the individual legs. Notwithstanding the provisions of Options 3, Section 10: (i) a Complex Options Strategies may be executed at a total credit or debit price with one other Member without giving priority to bids or offers established on the Exchange that are no better than the bids or offers in the individual options series comprising such total credit or debit; provided, however, that if any of the bids or offers established on the Exchange consist of a Priority Customer Order, the price of at least one leg of the complex strategy must trade at a price that is better than the corresponding bid or offer on the Exchange by at least one minimum trading increment for the series as defined in Options 3, Section 3; (ii) the option leg of a Stock-Option Strategy has priority over bids and offers for the individual options series established on the Exchange by Professional Orders and market maker quotes that are no better than the price of the options leg, but not over such bids and offers established by Priority Customer Orders; and (iii) the options legs of a Stock-Complex Strategy are executed in accordance with subparagraph (c)(2)(i).

[43] The allowance of a greater number of Market Complex Orders within the Opening Process provides a greater depth of price discovery for an options series. As noted above, the Boundary Price would assign limits to the Opening Price, therefore preventing Market Complex Orders which are aggressively priced from negatively impacting the Opening Price.

pursuant to MRX Options 3, Section 16(a).

Finally, with this proposal and as demonstrated in Example 5 above, a complex strategy would open pursuant to Supplementary Material .05(d)(5) of MRX Options 3, Section 14, with less contracts becoming subject to the Uncrossing pursuant to Supplementary Material .05(d)(6) of MRX Options 3, Section 14. As a result of this change, more interest would be able to trade within the Opening Process, ensuring a greater number of contracts are executed on MRX at the Complex Opening and lessening the likelihood that contracts which remain unmatched during the Complex Opening Price Determination process receive no execution in the Uncrossing due to changing market conditions.[44]

Phlx has a similar methodology to arrive at a complex opening price at Phlx Options 3, Section 14(d)(ii)(C)(2)[45] as compared to proposed Supplementary Material .05(d)(3) of MRX Options 3, Section 14. Phlx's COOP Evaluation and MRX's proposed Opening Price Determination both seek the price at which the maximum number of contracts can trade. Phlx's COOP Evaluation is an auction with a timer, unlike MRX's Opening Price Determination.[46] Proposed Supplementary Material .05(d)(3)(A) and (B) of MRX Options 3, Section 14 differs from Phlx Options 3, Section 14(d)(ii)(C)(2). MRX will open a complex strategy with the Complex Order Book crossed if an Opening Price cannot be found within the Boundary Prices and remain crossed while attempting to uncross the Complex Order Book on a best effort basis, pursuant to Supplementary Material .06 of MRX Options 3, Section 14, until all interest can be executed. Today, Phlx will open a complex strategy crossed when a price cannot be found within Phlx's cPBBO during the COOP Evaluation period and there are more aggressive away market prices that are limiting the ability to leg into the single-leg book, but will not remain crossed as complex orders that are through Phlx's cPBBO would be cancelled pursuant to Phlx Options 3, Section 14(f)(i)(A).[47]

The Exchange also proposes to amend the Opening Price in Supplementary Material .05(d)(4) of MRX Options 3, Section 14 that currently provides,

Opening Price. If the Potential Opening Price is at or within the Boundary Prices, the Potential Opening Price becomes the Opening Price. If the Potential Opening Price is not at or within the Boundary Prices, the Opening Price will be the price closest to the Potential Opening Price that satisfies the maximum quantity criteria without leaving unexecuted contracts on the bid or offer side of the market at that price and is at or within the Boundary Prices. If the bid Boundary Price is higher than the offer Boundary Price, or if no valid Opening Price can be found at or within the Boundary Prices, there will be no trade in the Complex Opening Price Determination and the complex strategy will open pursuant to the Complex Uncrossing Process described in Supplementary Material .06(b) to this Rule.

The Exchange proposes to amend this rule to instead provide,

If the Potential Opening Price is at or within the Boundary Prices, the Potential Opening Price becomes the Opening Price and the complex strategy will open pursuant to Supplementary Material .05(d)(5) to this Rule. If the bid Boundary Price is higher than the offer Boundary Price, or if no valid Potential Opening Price can be found at or within the Boundary Prices, there will be no trade in the Complex Opening Price Determination and the complex strategy will open pursuant to the Complex Uncrossing Process described in Supplementary Material .06(b) to this Rule.

With the proposed change, if the Potential Opening Price is at or within the Boundary Prices, the Potential Opening Price becomes the Opening Price and the complex strategy will open pursuant to the Uncrossing described in Supplementary Material .05(d)(5) of MRX Options 3, Section 14, as is the case today. However, as is the case today, if the bid Boundary Price is higher than the offer Boundary Price, or if no valid Potential Opening Price can be found at or within the Boundary Prices, there will be no trade in the Complex Opening Price Determination and the complex strategy will open pursuant to the Complex Uncrossing process described in Supplementary Material .06(b) of MRX Options 3, Section 14 pursuant to the proposed amendment to the Complex Opening Price Determination.

[44] Unmatched orders would rest on the Order Book with the potential to execute intra-day.

[45] COOP Evaluation. Upon expiration of the COOP Timer, the System will conduct a COOP Evaluation to determine, for a Complex Order Strategy, the price at which the maximum number of contracts can trade, taking into account Complex Orders marked All-or-None (which will be executed if possible) unless the maximum number of contracts can only trade without including All-or-None Orders. The Exchange will open the Complex Order Strategy at that price, executing marketable trading interest, in the following order: first, to Public Customers in time priority; next to Phlx electronic market makers on a pro rata basis; and then to all other participants on a pro rata basis. The imbalance of Complex Orders that are unexecutable at that price are placed on the CBOOK. (1) No trade possible. If at the end of the COOP Timer the System determines that no market or marketable limit Complex Orders or COOP Sweeps, Complex Orders or COOP Sweeps that are equal to or improve the cPBBO, and/or Complex Orders or COOP Sweeps that cross within the cPBBO exist in the System, all Complex Orders received during the COOP Timer will be placed on the CBOOK, as described in paragraph (f) below. (2) Trade is possible. If at the end of the COOP Timer the System determines that there are market or marketable limit Complex Orders or COOP Sweeps, Complex Orders or COOP Sweeps that are equal to or improve the cPBBO, and/or Complex Orders or COOP Sweeps that cross within the cPBBO in the System, the System will do the following: if such interest crosses and does not match in size, the execution price is based on the highest (lowest) executable offer (bid) price when the larger sized interest is offering (bidding), provided, however, that if there is more than one price at which the interest may execute, the execution price when the larger sized interest is offering (bidding) is the midpoint of the highest (lowest) executable offer (bid) price and the next available executable offer (bid) price rounded, if necessary, down (up) to the closest minimum trading increment. If the crossing interest is equal in size, the execution price is the midpoint of lowest executable bid price and the highest executable offer price, rounded, if necessary, up to the closest minimum trading increment. Executable bids/offers include any interest which could be executed at the net price without trading through residual interest or the cPBBO or without trading at the cPBBO where there is Public Customer interest at the best bid or offer for any leg, consistent with paragraph (c)(iii). If there is any remaining interest and there is no component that consists of the underlying security and provided that the order is not marked all-or-none, such interest may ''leg'' whereby each options component may trade at the PBBO with existing quotes and/or Limit Orders on the Limit Order book for the individual components of the Complex Order; provided that remaining interest may execute against any eligible Complex Orders received before legging occurs. If the remaining interest has a component that consists of the underlying security, such Complex Order will be placed on the CBOOK (as defined below). (3) The Complex Order Strategy will be open after the COOP even if no executions occur.

[46] Phlx's All-or-None order type differs from MRX's All-or-None order in that only Public Customers may utilize the Phlx All-or-None order type and Phlx's All-or-None order may rest on the order book. *See* Phlx Option 3, Section 7(b)(5). MRX's All-or-None order is a limit or market order that is to be executed in its entirety or not at all. *See* MRX Options 3, Section 7(c).

[47] By way of example, assume Phlx cPBBO is 1.00 × 2.00 and cNBBO is 1.45 × 1.50. Also, assume Phlx complex Day Order to buy the strategy @ $0.50 which begins a COOP timer. Next, a complex day order to sell the strategy @ $0.50 arrives during the COOP timer. These orders are crossed, but are not within Phlx's cPBBO, and, therefore, both orders cannot trade as part of the COOP Evaluation. Additionally, the sell order cannot leg into Phlx's simple order book because of the more aggressive cNBBO which would limit legging as part of the ACE price protection described within Phlx Options 3, Section 16(b)(i), and, therefore, the sell order that is crossed with Phlx's cPBBO cannot remain on the Complex Order Book and is ultimately cancelled. In contrast, on MRX, this sell order would remain crossed on the Complex Order Book while continuously looking for an opportunity to uncross and trade these Complex Orders as new orders arrive or the market moves. Options 3, Section 14 (f)(i)(A) provides that Complex Orders must be entered onto the CBOOK in increments of $0.01. The individual components of a Complex Order may be executed in minimum increments of $0.01, regardless of the minimum increments applicable to such components. Such orders will be placed on the CBOOK by the System when the following conditions exist: (A) When the Complex Order does not price-improve upon the cPBBO upon receipt. . .''.

Complex Order Risk Protections

The Exchange proposes a non-substantive amendment to the title of a Complex Order Risk Protection in MRX Options 3, Section 16, Complex Order Risk Protections. Specifically, the Exchange proposes to amend MRX Options 3, Section 16(c)(1) to change the title from ''Limit Order Price Protection'' to ''Complex Order Price Protection.'' The Exchange believes the proposed title more accurately describes the risk protection. The Exchange also proposes a non-substantive amendment to correct an incorrect citation in MRX Options 3, Section 16(b) to ''Options 2, Section 11.'' The correct citation is ''Options 3, Section 11.'' Correcting this citation will make clear what was [sic] section was being referenced.

Implementation

The Exchange intends to begin implementation of the proposed rule change prior to December 23, 2022. The implementation would commence with a limited symbol migration and continue to migrate symbols over several weeks. The Exchange will issue an Options Trader Alert to Members to provide notification of the symbols that will migrate and the relevant dates.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[48] in general, and furthers the objectives of Section 6(b)(5) of the Act,[49] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest for the reasons discussed below.

Legging Order

Amending MRX Options 3, Section 7(k)(1) to add a provision which states that a Legging Order will not be generated during a Posting Period in progress on the same side in the series pursuant to Options 3, Section 15 regarding Acceptable Trade Range, is consistent with the Act because from a System processing and user acceptance standpoint, the best practice is to wait for the ATR Posting Period to complete before attempting to generate a Legging Order on the same side in the series, as the time required to complete the ATR Posting Period is minimal. The proposed change is designed to protect investors and the public interest as automatically generated Legging Orders would be removed from the single-leg order book when they are no longer at the Exchange's displayed best bid or offer. Generating a Legging Order during a Posting Period in progress on the same side in the series would lead to the immediate removal of the Legging Order from the single-leg order book, making it superfluous to have been generated. Phlx's legging order rule in Options 3, Section 14(f)(iii)(C)(2)[50] has the same restriction on generating legging orders as proposed herein.

Changes to the Single-Leg Price Improvement Mechanism for Crossing Transactions

The Exchange's proposal to amend MRX Options 3, Section 13(d)(4), related to single-leg PIM, to not permit unrelated marketable interest, on the opposite side of the market from the Agency Order, which is received during a single-leg PIM to early terminate a single-leg PIM is consistent with the Act and promotes just and equitable principles because allowing the auction to run its full course would provide a full opportunity for price improvement to the Crossing Transaction. The unrelated interest would participate in the single-leg PIM allocation pursuant to MRX Options 3, Section 13(d), if residual contracts remain after executing with interest on the single-leg order book. Today, Phlx[51] and BX[52] do not permit unrelated interest on the same or opposite side of an Agency Order to early terminate their simple price improvement auctions.

The proposed amendment in MRX Options 3, Section 13(c)(5)(ii), related to single-leg PIM, applies to the receipt of marketable orders both on the same side and opposite side of the Agency order. With respect to the same side of the Agency Order, today, an unrelated market or marketable limit order in the same series on the same side of the Agency Order would cause the single-leg PIM to early terminate as well. The proposal promotes just and equitable principles of trade because a market or marketable limit order in the same series on the same side of the Agency Order cannot interact with a single-leg PIM auction. The market or marketable limit order may interact with the order book, and if there are residual contracts that remain from the market or marketable order in the same series on the same side of the Agency Order, they will rest on the order book and improve the BBO beyond the price of the Crossing Transaction which will cause early termination of the single-leg PIM pursuant to proposed MRX Options 3, Section 13(c)(5)(ii). The Exchange believes that this outcome would allow for the single-leg PIM exposure period to continue for the full period despite the receipt of unrelated marketable interest on the same side of the market from the Agency Order, provided residual interest does not go on to rest on the order book improving the BBO beyond the price of the Crossing Transaction of the PIM. Allowing the single-leg PIM to run its full course protects investors and the general public because it would provide an opportunity for price improvement to the Agency Order.

Amending current MRX Options 3, Section 13(c)(5)(iii) to align the rule text more closely with BX Options 3, Section 13(ii)(B)(2)[53] is consistent with the Act because it removes any ambiguity that a market or marketable limit order priced more aggressively than the Agency Order on the same side could ultimately rest on the order book, improving the BBO beyond the price of the Crossing Transaction of the PIM and, therefore, cause the early termination of a single-leg PIM. Continuing to not permit a single-leg PIM to early terminate any time the Exchange best bid or offer improves beyond the price of the Crossing Transaction on the same side of the market as the Agency Order protects investors and the general public because the Crossing Transaction Agency Order's price is inferior to the Exchange's best bid or offer on the same side of the market as the Agency Order. Upon early termination of the single-leg PIM, the Crossing Transaction would execute against responses that arrived prior to the time the Exchange's best bid or offer improved beyond the Crossing Transaction. The proposed amendment to the rule text is not intended to amend the current System functionality, rather it is intended to make clear that a market or marketable limit order could ultimately rest on the order book and improve the BBO beyond the price of the Crossing Transaction.

Adding proposed new MRX Options 3, Section 13(c)(5)(iii), which describes the automatic termination of the exposure period resulting from a trading halt on the Exchange in the affected series, is consistent with the Act because a trading halt would cause an option series to stop trading on MRX and thereby impact the PIM auction. Today, if a trading halt is initiated after an order is entered into the single-leg PIM, such auction will be automatically terminated without execution. Of note, the Exchange is separately[54] proposing to amend MRX Options 3, Section

[48] 15 U.S.C. 78f(b).

[49] 15 U.S.C. 78f(b)(5).

[50] *See* note 8 above.

[51] *See* note 14 above.

[52] *See* note 15 above.

[53] *See* note 17 above.

[54] *See* note 19 above.

13(d)(5) to change System behavior such that if a trading halt is initiated after an order is entered into the single-leg PIM, such auction will be automatically terminated with execution solely with the Counter-Side Order.[55] The proposed amendment to MRX Options 3, Section 13(c)(5)(iii) protects investors and the general public by making clear that a trading halt would lead to early termination of a single-leg PIM. This amendment is not intended to amend the current System functionality, rather it is intended to make clear that a trading halt will cause the single-leg PIM to early terminate.

Changes to the Complex PIM

Deleting MRX Options 3, Section 13(e)(4)(vi) within Complex PIM, as well as a paragraph in Supplementary Material .01(b)(ii) of MRX Options 3, Section 14 discussing Complex Order Exposure, related to the early termination of single-leg PIM from the arrival of unrelated marketable interest on either the same or opposite side of the market from the Agency Order, is consistent with the Act because a single-leg PIM will no longer early terminate from the arrival of unrelated marketable interest on either the same or opposite side of the market from the Agency Order and because the flash functionality will no longer exist.[56] The removal of the aforementioned rule text will protect investors and the public by avoiding confusion as the scenarios contemplated by MRX Options 3, Section 13(e)(4)(vi) and Supplementary Material .01(b)(ii) of MRX Options 3, Section 14 will no longer be able to occur.

Complex Orders Delayed Functionality

The Exchange's proposal to delay the implementation of certain stock-tied functionality in connection with the technology migration is consistent with the Act as it will allow the Exchange additional time to code, test and implement this functionality on the enhanced platform. Delayed Functionalities would not be available for symbols that migrated to the platform and thereafter, until such time as the Exchange recommenced their availability by announcing a date in an Options Trader Alert, which date would be prior to one year from the start of the migration of the symbols to the platform. The Exchange's proposal to delay these functionalities protects investor and the general public by allowing the Exchange to stage the migration, thereby providing maximum benefit to its Members while also ensuring a successful rollout.

Other Complex Order Amendments

Opening Only Complex Order

The Exchange's proposal to remove the word ''Limit'' within the description of the Opening Only Complex Order Type in MRX Options 3, Section 14(b)(10) is consistent with the Act because it allows Opening Only Complex Orders to be submitted as Market Orders or Limit Orders. The Exchange believes that allowing Market and Limit Orders to be submitted within the Complex Opening Process promotes just and equitable principles of trade. Market Orders are typically the most aggressively priced orders while Limit Orders have a limit price contingency that Market Orders do not have. Allowing both of these order types to participate in the Complex Opening Process protects investors and the general public because it allows greater liquidity to be present to determine the Opening Price. All Members may enter both Market Orders and Limit Orders in the Complex Opening Process as well as intra-day. This proposal is consistent with current System operations.

Complex QCC With Stock Orders

The Exchange's proposal to amend an incorrect citation with MRX Options 3, Section 14(b)(15), related to Complex QCC with Stock Orders, is consistent with the Act because the current citation to MRX Options 3, Section 12(e) in the description of this order type should be to MRX Options 3, Section 12(f). This non-substantive amendment will make clear what was meant by the reference.

Complex Preferenced Orders

The Exchange's proposal to add ''Complex Preferenced Orders'' to the list of Complex Order Types in MRX Options 3, Section 14(b) is consistent with the Act because the Exchange believes that this order type will promote just and equitable principles of trade because the order type will continue to encourage Preferred Market Makers to quote aggressively in an effort to execute against the Complex Preferenced Order. Preferred Marker Makers are not able to ascertain if a particular order is a Complex Preferenced Order. The Exchange believes the proposal will protect investors and the general public by encouraging greater order flow to be sent to the Exchange through Complex Preferenced Orders and that this increased order flow will benefit all market participants on the Exchange because they may interact with that order flow.

The proposal promotes just and equitable principles of trade because it continues to prioritize Priority Customer[57] Orders on the single-leg order book. Priority Customers have priority over non-Priority Customer interest at the same price in the same options series on the single-leg order book.[58] Complex Preferenced Orders are allocated based on the competitive bidding of market participants. The Exchange's proposal promotes just and equitable principles of trade as a Preferred Marker Maker must be at the NBBO for a component leg(s) of the Complex Preferenced Order at the time the Complex Preferenced Order is received. Moreover, participation entitlements for Preferred Market Makers are designed to balance the obligations[59] that the Preferred Market Maker has to the market with corresponding benefits. In its approval of other options exchange preferenced or directed order programs, the Commission has, like proposals to amend a specialist guarantee, focused on whether the percentage of the ''entitlement'' would rise to a level that could have a material adverse impact on quote competition within a particular exchange, and concluded that such programs do not jeopardize market integrity or the incentive for market participants to post competitive quotes.[60]

Further, adding this existing order type, which is described in MRX Options 2, Section 10, would complete the list of Complex Order types in MRX

[55] SR–MRX–2022–5P proposes to renumber MRX Options 3, Section 13(d)(5) as Options 3, Section 13(d)(6), and proposes to state, ''Specifically, current MRX Options 3, Section 13(d) is proposed to be renumbered within SR–MRX–2022–5P to Options 3, Section 13(d)(6) and proposes to state, ''If a trading halt is initiated after an order is entered into the Price Improvement Mechanism, such auction will be automatically terminated with execution solely with the Counter-Side Order.''

[56] *See* note 24 above.

[57] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Options 1, Section 1(a)(36).

[58] *See* MRX Options 3, Section 10(c)(1)(A).

[59] Primary Market Makers are obligated to quote in the Opening Process pursuant to MRX Options 3, Section 8(c) as well as intra-day pursuant to Options 2, Section 5(e), in addition to other obligations noted within MRX Options 2, Sections 4–8.

[60] *See* Securities Exchange Act Release Nos. 74129 (January 23, 2015), 80 FR 4954 at 4955 (January 29, 2015) (SR–BX–2014–049) (Order Approving Proposed Rule Change Relating to Directed Market Makers); and 51759 (May 27, 2005), 70 FR 32860 at 32861(June 6, 2005) (SR–Phlx–2004–91) (Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 1 Thereto To Establish a Directed Order Process for Orders Delivered to the Phlx Via AUTOM).

Options 3, Section 14(b). The addition of Complex Preferenced Orders to the list of order types in MRX Options 3, Section 14(b) will make clear to Members the availability of Complex Preferenced Orders. Both Phlx [61] and MIAX [62] have a similar order type.

Options 3, Section 14(c)(2) and MRX Supplementary Material .02 to Options 3, Section 14

Correcting an incorrect reference to ''ISE'' with MRX Options 3, Section 14(c)(2), which should be to ''MRX,'' will add clarity to the rule; this amendment is non-substantive. The Exchange's proposal to make a technical correction in Supplementary Material .02 of MRX Options 3, Section 14 to amend the word ''which'' to ''whom'' is a non-substantive amendment.

Complex Opening Price Determination

The Exchange's proposal to amend the citation within Supplementary Material .05(d)(2) to Options 3, Section 14, related to the Potential Opening Price, is consistent with the Act because the current citation to Supplementary Material .06(b) should be to Supplementary Material .05(b). This non-substantive amendment will make clear what was meant by the reference.

The Exchange's proposal to amend Supplementary Material .05(d)(3) of MRX Options 3, Section 14, which describes the Complex Opening Price Determination, is consistent with the Act because the proposed new Complex Opening Process would allow for additional contracts to be included in the Potential Opening Price calculation. This proposed methodology would protect investors and the general public by leading to better price discovery and more contracts executing as part of the Complex Opening Price Determination. With this proposal, when the interest does not match the size and there is more than one Potential Opening Price at which the interest may execute, then the Exchange would calculate a Potential Opening Price using the mid-point of the highest (lowest) executable offer (bid) price and the next available executable offer (bid) price rounded, if necessary, down (up) to the closest minimum trading increment. As a result, the proposal promotes just and equitable principles of trade as more options contracts are likely to be executed at better prices than under current rule. This behavior differs from MRX's current opening rule in that, today, the Exchange would calculate the Potential Opening Price as the highest (lowest) executable bid (offer) when there would be contracts left unexecuted on the bid (offer) side of the complex market. The proposed methodology is similar to Phlx.[63]

Further, the proposed amendment promotes just and equitable principles of trade by allowing Market Complex Orders to participate in the Opening Price Determination process in a broader capacity than the MRX opening rule allows for today. Today, if there are only Market Complex Orders on both sides of the market, or if there are Market Complex Orders on the bid (offer) side of the market for greater than the total size of Complex Orders on the offer (bid) side of the market, then MRX will not trade in the Complex Opening Price Determination process and would instead open pursuant to an Uncrossing pursuant to Supplementary Material .06(b) of MRX Options 3, Section 14. The proposed rule would have the Boundary Price assign limits to the Opening Price and, therefore, permit Market Complex Orders to participate in the Complex Opening Process, without limitation to the benefit of investors and the public interest. With this change, MRX would permit a complex strategy to calculate an Opening Price utilizing a greater number of Market Complex Orders, which benefits the Opening Process by taking into account these more aggressively priced orders [64] while also bringing more liquidity into the Opening Price calculation. The amendment is designed to promote just and equitable principles of trade as it will benefit Members by smoothing the way for the complex strategy to open with Market Complex Orders.

Finally, the proposed amendments to the Complex Opening Process should promote just and equitable principles by allowing a complex strategy to open pursuant to Supplementary Material .05(d)(4) of MRX Options 3, Section 14, with less contracts becoming subject to the Uncrossing pursuant to Supplementary Material .05(d)(5) of MRX Options 3, Section 14. As a result of this change, more interest would be able to trade within the Opening Process, ensuring a greater number of contracts are executed on MRX at the opening and lessening the likelihood that contracts which remain unmatched during the Uncrossing receive no execution.[65]

Complex Order Risk Protections

The Exchange's proposal to amend the title of a Complex Order Risk Protection in Options 3, Section 16, Complex Order Risk Protections is a non-substantive amendment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Legging Orders

Amending MRX Options 3, Section 7(k)(1) to add a provision which states that a Legging Order will not be generated during a Posting Period in progress on the same side in the series pursuant to Options 3, Section 15 regarding Acceptable Trade Range does not impose an undue burden on intra-market competition because the amendment will apply equally to all Members as Legging Orders are generated by the System.

Additionally, this proposal does not impose an undue burden on inter-market competition as other options exchanges may adopt Legging Orders and similar rules for the generation of such orders. Today, Phlx's legging order rule in Options 3, Section 14(f)(iii)(C)(2) has the same restriction as proposed to be added to MRX's Legging Order rule in MRX Options 3, Section 7(k)(1).[66]

Changes to the Single-Leg Price Improvement Mechanism for Crossing Transactions

The Exchange's proposal to amend MRX Options 3, Section 13(d)(4), MRX Options 3, Section 13(c)(5)(ii) and (iii), and add a proposed new MRX Options 3, Section 13(c)(5)(iii), related to single-leg PIM, does not impose an undue burden on intra-market competition because the amendment will apply equally to all Members. All Members may utilize PIM.

The Exchange's proposal to amend MRX Options 3, Section 13(d)(4), MRX Options 3, Section 13(c)(5)(ii) and (iii), and add a proposed new MRX Options 3, Section 13(c)(5)(iii), related to single-leg PIM, does not impose an undue burden on inter-market competition because other options exchanges may adopt similar rules. Today, Phlx [67] and

[61] *See* note 36 above.

[62] *See* note 37 above.

[63] *See* Phlx Options 3, Section 14(d)(ii)(C)(2).

[64] The allowance of a greater number of Market Complex Orders within the Opening Process provides a greater depth of price discovery for an options series. As noted above, the Boundary Price would assign limits to the Opening Price, therefore preventing Market Complex Orders which are aggressively priced from negatively impacting the Opening Price.

[65] Unmatched orders would rest on the order book with the potential to execute intra-day.

[66] *See* note 8 above.

[67] *See* note 14 above.

BX[68] do not permit unrelated marketable interest on either the same or opposite side of the market from an Agency Order to early terminate their simple price improvement auctions.

Changes to the Complex PIM

Deleting MRX Options 3, Section 13(e)(4)(vi) within Complex PIM, as well as a related paragraph in Supplementary Material .01(b)(ii) of MRX Options 3, Section 14, which describes Complex Order Exposure, related to the early termination of single-leg PIM as a result of the arrival of unrelated marketable interest on either the same or the opposite side of the market from the Agency Order does not impose an undue burden on intra-market competition because the amendment will apply equally to all Members. All Members may utilize Complex PIM.

Deleting MRX Options 3, Section 13(e)(4)(vi) within Complex PIM, as well as a related paragraph in Supplementary Material .01(b)(ii) of MRX Options 3, Section 14, which describes Complex Order Exposure, related to the early termination of single-leg PIM from the arrival of unrelated marketable interest on either the same or opposite side of the market from the Agency Order does not impose an undue burden on inter-market competition as other options exchanges may adopt similar rules. Today, Phlx[69] and BX[70] do not permit unrelated marketable interest on either the same or opposite side of the market from an Agency Order to early terminate their simple price improvement auctions.

Complex Orders Delayed Functionality

The Exchange's proposal to delay the implementation of certain stock-tied functionality in connection with the technology migration does not impose an undue burden on intra-market competition because no Member will be able to utilize the Delayed Functionalities.

The Exchange's proposal to delay the implementation of certain stock-tied functionality in connection with the technology migration does not impose an undue burden on inter-market competition because the Exchange does not believe that the proposed rule change will impact the intense competition that exists in the options market. Today, ISE offers the Delayed Functionalities.

Other Complex Order Amendments

The Exchange does not believe that the proposed amendments to the Complex Orders rule will impose any significant burden on inter-market competition. Other exchanges today offer complex order functionalities. These options markets may amend their rules to mirror those of MRX. Other options exchanges offer orders similar to Complex Preferenced Orders.[71] Additionally, the proposed Complex Opening Process is similar to Phlx.[72] Finally, the proposed Complex Opening Process methodology would allow MRX to compete with other options exchanges that offer Complex Order functionality.

Opening Only Complex Order

The Exchange's proposal to remove the word ''Limit'' within the description of the Opening Only Complex Order Type in MRX Options 3, Section 14(b)(10) does not impose an undue burden on intra-market competition because this proposed change will apply to all Members.

Complex QCC With Stock Orders

The Exchange's proposal to amend an incorrect citation with MRX Options 3, Section 14(b)(15), related to Complex QCC with Stock Orders, does not impose an undue burden on intra-market competition because the amendment is non-substantive.

Complex Preferenced Orders

The Exchange's proposal to add ''Complex Preferenced Orders'' to the list of Complex Order Types in MRX Options 3, Section 14(b) does not impose an undue burden on intra-market competition. Preferred Market Makers have obligations[73] unlike other market participants. The allocation entitlements for Preferred Market Makers are designed to balance the obligations that the Preferred Market Makers has to the market with corresponding benefits. In order to receive the participation entitlement for a Complex Preferenced Order, Preferred Market Makers are required to quote 90% of the trading day as compared to Market Makers who are required to quote 60% of the trading day.[74] Further, Priority Customers[75] have priority over non-Priority Customer interest at the same price in the same options series on the single-leg order book.[76]

At the time of receipt of the Complex Preferenced Order, a Preferred Market Maker would have to be quoting at the NBBO, which is intended to incentivize the Preferred Market Maker to quote aggressively in order to execute against the Complex Preferenced Order. Preferred Marker Makers are not able to ascertain if a particular order is a Complex Preferenced Order. The Exchange believes the proposal will encourage Market Makers to quote tighter and add a greater amount of liquidity on MRX in an attempt to interact with Complex Preferenced Orders that are sent to the Exchange. This order flow will benefit all market participants on the Exchange because any MRX Member may interact with that order flow. Finally, any MRX Member on the single-leg or Complex Order Book may trade with a Complex Preferenced Order. Also, any MRX Market Maker may elect to receive Preferenced Order.

Options 3, Section 14(c)(2) and MRX Supplementary Material .02 to Options 3, Section 14

Correcting an incorrect reference to ''ISE'' with MRX Options 3, Section 14(c)(2), which should be to ''MRX,'' will add clarity to the rule; this amendment is non-substantive. The Exchange's proposal to make a technical correction in Supplementary Material .02 of MRX Options 3, Section 14 to amend the word ''which'' to ''whom'' is a non-substantive amendment.

Complex Opening Price Determination

The Exchange's proposal to amend an incorrect citation within Supplementary Material .05(d)(2) to Options 3, Section 14, related to the Potential Opening Price, does not impose an undue burden on intra-market competition because the amendment is non-substantive.

The Exchange's proposal to amend Supplementary Material .05(d)(3) to MRX Options 3, Section 14, which describes the Complex Opening Price Determination, does not impose an undue burden on intra-market competition because all Members may submit interest into the Complex Opening Process.

Complex Order Risk Protections

The Exchange's proposal to amend the title of a Complex Order Risk Protection in Options 3, Section 16, Complex Order Risk Protections is a non-substantive amendment.

[68] *See* note 15 above.

[69] *See* note 14 above.

[70] *See* note 15 above.

[71] *See e.g.,* Phlx Options 2, Section 10 and MIAX Rule 100.

[72] *See* Phlx Options 3, Section 14(d)(ii)(C)(2).

[73] *See* MRX Options 2, Section 5.

[74] *See* MRX Options 2, Section 5.

[75] *See* note 57 above.

[76] *See* MRX Options 3, Section 10(c)(1)(A).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2022–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2022–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2022–10, and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[77]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16257 Filed 7–28–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95362; File No. SR–NYSENAT–2022–12]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates

July 25, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 12, 2022, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Rebates (''Fee Schedule'') related to colocation to remove obsolete text. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule related to colocation to remove obsolete text.[4]

(1) Proposal To Change Names of Select Third Party Systems and Third Party Data Feeds

As set forth in the Fee Schedule, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[5] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Fee Schedule.

The Exchange proposes to amend the list of Third Party Systems in the Fee Schedule to reflect the following updated names for existing Third Party Systems:

- Change the name of the ''Miami International Securities Exchange'' to ''MIAX Options,'' and
- Change the name of the ''MIAX PEARL'' to ''MIAX PEARL Options.''

The Exchange also proposes to amend the list of Third Party Data Feeds in the Fee Schedule to reflect the following

[77] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc., has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–30, SR–NYSEAMER–2022–31, SR–NYSEArca–2022–41, and SR–NYSECHX–2022–17.

[5] *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07).

updated names for existing Third Party Data Feeds:

• Change the name ''Miami International Securities Exchange/MIAX PEARL'' to ''MIAX Options/MIAX PEARL Options;'' and

• Change ''SR Labs—SuperFeed'' data feeds to ''Vela—SuperFeed,'' to reflect the content provider's recent change to the name of these products.

This change would update the names of these services, but would not make any change to the services provided.

(2) Proposal To Delete Discontinued Third Party Data Feed

The Exchange proposes to delete the ''NASDAQ OMDF'' data feed from the list of available Third Party Data Feeds, as it is no longer offered by the content service provider.

(3) Proposal To Remove References to ICE Data Global Index

The Exchange proposes to remove obsolete references to the ICE Data Global Index (the ''GIF'') from the list of Third Party Data Feeds available for connectivity and related text.

In May 2020, ICE, which publishes the GIF, announced to its customers that before the end of 2020, it would cease offering the GIF as a stand-alone product. The Exchange accordingly amended its Fee Schedule to inform customers that it would cease offering connectivity to the GIF once it is no longer available.[6]

ICE has informed the Exchange that it ceased offering the GIF as a stand-alone product, making the references to the GIF obsolete. The operative date was announced through a customer notice. Accordingly, the Exchange proposes to remove ''ICE Data Global Index*'' and the corresponding asterisked note from the Fee Schedule.

In order to implement the proposed change, the Exchange proposes to make the following changes to the section of the Fee Schedule entitled ''Connectivity to Third Party Data Feeds'':

• In the first paragraph and in the table of Third Party Data Feeds, delete ''ICE Data Global Index * ''.

• Following the table of Third Party Data Feeds, delete the following text:

** ICE will cease to offer the GIF as a stand-alone product, which the Exchange has been informed by ICE is currently expected to occur before the end of 2020. The Exchange will announce the operative date through a customer notice. Any change fees that a User would otherwise incur as a result of the proposed change will be waived.*

(4) Proposal To Remove the Temporary Waiver of Hot Hands Fees

The Exchange proposes to remove the obsolete reference to the waiver of Hot Hands fees in light of the reopening of the data center in Mahwah, New Jersey (''Mahwah Data Center'' or ''MDC'').

In March 2020, ICE announced to each User that, starting on March 16, 2020, the MDC would be closed to third parties in response to COVID–19. The Exchange temporarily waived all Hot Hands fees from the date of the closing through the date of the reopening of the MDC, and added a note to the fees for the Hot Hands service stating as much.[7]

The MDC reopened on October 1, 2020. The date of the reopening was announced through a customer notice. As a result of the reopening, the waiver of Hot Hands fees ceased, and the note became obsolete. The Exchange now proposes to remove the obsolete text.

In order to implement this proposed change, the Exchange proposes to make the following changes to the Fee Schedule:

• In the Types of Service table, remove the ''†'' symbol after ''Hot Hands Service ***''.

• Following the Types of Service table, remove the following text:

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the reopening of the Mahwah, New Jersey data center. The date of the reopening will be announced through a customer notice.

(5) Proposal To Remove Obsolete Text About Transition Period for Suspended Services

The Exchange proposes to remove obsolete text regarding the transition period that expired on May 24, 2021 concerning the Exchange's provision of suspended services at no charge.

As background, on March 10, 2021, the Exchange filed with the Commission a proposed rule change for immediate effectiveness that amended the colocation services offered by the Exchange to provide Users the option to access the systems and data feeds of various additional third parties.[8] The proposed rule change became operative on April 9, 2021, and five Users subsequently contracted to receive the services that were added in the filing.

On May 7, 2021, the Commission suspended the filing and instituted proceedings to determine whether the proposed rule change should be approved or disapproved.[9] Such action suspended the Exchange's ability to offer access to Third Party Systems from Long Term Stock Exchange, Members Exchange, MIAX Emerald, MIAX PEARL Equities, Morgan Stanley, and TD Ameritrade, and to offer connectivity to Third Party Data Feeds from ICE Data Services—ICE TMC, Members Exchange, MIAX Emerald, and MIAX PEARL Equities (together, the ''Suspended Services'').

On May 12, 2021, the Commission approved for immediate effectiveness the Exchange's filing proposing to provide the Suspended Services to all Users, at no charge, for a period of 14 days (''Transition Period'') through May 24, 2021, to enable current Users to maintain their connectivity while establishing alternate connectivity.[10]

Given that the Transition Period has expired, the Exchange proposes to remove the obsolete text regarding this provision. To that end, the Exchange proposes to delete the following text:

Connectivity to Suspended Third Party Systems and Suspended Third Party Data Feeds

Connectivity to the Third Party Systems and Third Party Data Feeds listed below (''Suspended Services'') is available until May 24, 2021 (''Transition Period''). During the Transition Period, the Exchange will not charge any fees for the Suspended Services. At the conclusion of the Transition Period, any remaining customers of Suspended Services will have their Suspended Services terminated.

Suspended Third Party Systems
Long Term Stock Exchange (LTSE)
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities
Morgan Stanley
TD Ameritrade

Suspended Third Party Data Feeds
ICE Data Services—ICE TMC
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities

(6) Proposal To Remove LCN Access—1 Gb Circuit

The Exchange proposes to delete the service ''LCN Access—1 Gb Circuit''

[6] *See* Securities Exchange Act Release No. 88981 (June 1, 2020), 85 FR 34690 (June 5, 2020) (SR–NYSENAT–2020–19).

[7] The Exchange first waived the Hot Hands Fee in a March 17, 2020 filing, and subsequently extended the waiver four times. *See* Securities Exchange Act Release Nos. 88399 (March 17, 2020), 85 FR 16428 (March 23, 2020) (SRNYSENAT–2020–10); 88521 (March 31, 2020), 85 FR 19194 (April 6, 2020) (SR–NYSENAT–2020–14); 88958 (May 27, 2020), 85 FR 33764 (June 2, 2020) (SR–NYSENAT–2020–18); 89175 (June 29, 2020), 85 FR 40354 (July 6, 2020) (SR–NYSENAT–2020–20); and 89653 (August 25, 2020), 85 FR 53874 (SRNYSENAT–2020–26).

[8] *See* Securities Exchange Act Release No. 91389 (March 23, 2021), 86 FR 16403 (March 29, 2021) (SR–NYSENat–2021–05).

[9] *See* Securities Exchange Act Release No. 91790 (May 7, 2021) (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSECHX–2021–04, SR–NYSENAT–2021–05).

[10] *See* Securities Exchange Act Release No. 91863 (May 12, 2021) (SR–NYSE–2021–13).

from the list of available types of services. The number of 1 Gb LCN ports purchased by Users has steadily declined from 4 in 2017, to 2 in 2018, to 1 in 2021, to zero currently. The Exchange understands that this fall-off in demand for the 1 Gb LCN port is due to the fact that market data feeds continue to increase in bandwidth, such that Users prefer to purchase larger port sizes. Indeed, the last remaining User with a 1 Gb LCN port discontinued that port in June 2022 and has switched to a 10 Gb LCN port instead. The Exchange believes that there is no remaining User demand for the 1 Gb LCN port, and accordingly, the Exchange proposes to discontinue the service as obsolete.

Application and Impact of the Proposed Changes

The Exchange does not expect that the proposed changes would have any impact. The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users [11] equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that updating the names of existing Third Party Services and Third Party Data Feeds and removing obsolete text from the Fee Schedule would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Updating the names of the Third Party Services and Third Party Data Feeds at issue will enhance the clarity and transparency of the Fee Schedule and reduce potential customer confusion. Removing obsolete references to (i) the GIF and its associated fee, (ii) the note regarding the Hot Hands service, and (iii) the availability of the Suspended Services would make it easier to read, understand, and administer the Fee Schedule, enhancing its clarity and transparency and alleviating possible customer confusion.

Similarly, the Exchange believes that discontinuing offering the 1 Gb LCN connection would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb LCN connection has declined in recent years and there are currently no Users that subscribe to the service. The Exchange does not expect demand to rebound given Users' overall preference for larger port sizes to accommodate larger market data feeds. Removing references to the fees for this obsolete service from the Price List would make the Price List easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would update obsolete product names, delete obsolete services, and remove obsolete text from the Fee Schedule, in order to enhance transparency and alleviate potential customer confusion.

The Exchange believes that updating the names of existing Third Party Systems and Third Party Data Feeds and removing obsolete text from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the names of the existing systems and data feeds at issue would be updated and clarified in the Fee Schedule for all Users; the obsolete 1 Gb LCN connection would be removed for all Users; and obsolete text regarding the GIF, the note to the Hot Hands service, and the availability of the Suspended Services would be removed from the Fee Schedule as to all Users.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services and product names.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

[11] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* 83 FR 26314, *supra* note 4, at 26314 n.9. As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(8).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2022–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2022–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–12 and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

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BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95360; File No. SR–NYSEArca–2022–41]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges and the NYSE Arca Options Fees and Charges

July 25, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 12, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges and the NYSE Arca Options Fees and Charges (together, the ''Fee Schedules'') related to co-location to related to colocation to remove obsolete text. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedules related to colocation to remove obsolete text.[4]

(1) Proposal To Change Names of Select Third Party Systems and Third Party Data Feeds

As set forth in the Fee Schedules, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[5] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Fee Schedules.

The Exchange proposes to amend the list of Third Party Systems in the Fee Schedules to reflect the following updated names for existing Third Party Systems:

- Change the name of the ''Miami International Securities Exchange'' to ''MIAX Options,'' and
- Change the name of the ''MIAX PEARL'' to ''MIAX PEARL Options.''

The Exchange also proposes to amend the list of Third Party Data Feeds in the Fee Schedules to reflect the following updated names for existing Third Party Data Feeds:

- Change the name ''Miami International Securities Exchange/MIAX PEARL'' to ''MIAX Options/MIAX PEARL Options;'' and

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–30, SR–NYSEAMER–2022–31, SR–NYSECHX–2022–17, and SR–NYSENAT–2022–12.

[5] *See* Securities Exchange Act Release No. 80310 (March 24, 2017, 82 FR 15763 (March 30, 2017) (SR–NYSEArca–2016–89).

• Change ''SR Labs—SuperFeed'' data feeds to ''Vela—SuperFeed,'' to reflect the content provider's recent change to the name of these products.

This change would update the names of these services, but would not make any change to the services provided.

(2) Proposal To Delete Discontinued Third Party Data Feed

The Exchange proposes to delete the ''NASDAQ OMDF'' data feed from the list of available Third Party Data Feeds, as it is no longer offered by the content service provider.

(3) Proposal To Remove References to ICE Data Global Index

The Exchange proposes to remove obsolete references to the ICE Data Global Index (the ''GIF'') from the list of Third Party Data Feeds available for connectivity and related text.

In May 2020, ICE, which publishes the GIF, announced to its customers that before the end of 2020, it would cease offering the GIF as a stand-alone product. The Exchange accordingly amended the Fee Schedules to inform customers that it would cease offering connectivity to the GIF once it is no longer available.[6]

ICE has informed the Exchange that it ceased offering the GIF as a stand-alone product, making the references to the GIF obsolete. The operative date was announced through a customer notice. Accordingly, the Exchange proposes to remove ''ICE Data Global Index*'' and the corresponding asterisked note from the Fee Schedules.

In order to implement the proposed change, the Exchange proposes to make the following changes to the sections of the Fee Schedules entitled ''Connectivity to Third Party Data Feeds'':

• In the first paragraph and in the table of Third Party Data Feeds, delete ''ICE Data Global Index*''.

• Following the table of Third Party Data Feeds, delete the following text:

** ICE will cease to offer the GIF as a stand-alone product, which the Exchange has been informed by ICE is currently expected to occur before the end of 2020. The Exchange will announce the operative date through a customer notice. Any change fees that a User would otherwise incur as a result of the proposed change will be waived.*

(4) Proposal To Remove the Temporary Waiver of Hot Hands Fees

The Exchange proposes to remove the obsolete reference to the waiver of Hot Hands fees in light of the reopening of the data center in Mahwah, New Jersey (''Mahwah Data Center'' or ''MDC'').

In March 2020, ICE announced to each User that, starting on March 16, 2020, the MDC would be closed to third parties in response to COVID–19. The Exchange temporarily waived all Hot Hands fees from the date of the closing through the date of the reopening of the MDC, and added a note to the fees for the Hot Hands service stating as much.[7]

The MDC reopened on October 1, 2020. The date of the reopening was announced through a customer notice. As a result of the reopening, the waiver of Hot Hands fees ceased, and the note became obsolete. The Exchange now proposes to remove the obsolete text.

In order to implement this proposed change, the Exchange proposes to make the following changes to the Fee Schedules:

• In the Types of Service table, remove the ''†'' symbol after ''Hot Hands Service* * *''.

• Following the Types of Service table, remove the following text:

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the reopening of the Mahwah, New Jersey data center. The date of the reopening will be announced through a customer notice.

(5) Proposal To Remove Obsolete Text About Transition Period for Suspended Services

The Exchange proposes to remove obsolete text regarding the transition period that expired on May 24, 2021 concerning the Exchange's provision of suspended services at no charge.

As background, on March 10, 2021, the Exchange filed with the Commission a proposed rule change for immediate effectiveness that amended the colocation services offered by the Exchange to provide Users the option to access the systems and data feeds of various additional third parties.[8] The proposed rule change became operative on April 9, 2021, and five Users subsequently contracted to receive the services that were added in the filing.

On May 7, 2021, the Commission suspended the filing and instituted proceedings to determine whether the proposed rule change should be approved or disapproved.[9] Such action suspended the Exchange's ability to offer access to Third Party Systems from Long Term Stock Exchange, Members Exchange, MIAX Emerald, MIAX PEARL Equities, Morgan Stanley, and TD Ameritrade, and to offer connectivity to Third Party Data Feeds from ICE Data Services—ICE TMC, Members Exchange, MIAX Emerald, and MIAX PEARL Equities (together, the ''Suspended Services'').

On May 12, 2021, the Commission approved for immediate effectiveness the Exchange's filing proposing to provide the Suspended Services to all Users, at no charge, for a period of 14 days (''Transition Period'') through May 24, 2021, to enable current Users to maintain their connectivity while establishing alternate connectivity.[10]

Given that the Transition Period has expired, the Exchange proposes to remove the obsolete text regarding this provision. To that end, the Exchange proposes to delete the following text:

Connectivity to Suspended Third Party Systems and Suspended Third Party Data Feeds

Connectivity to the Third Party Systems and Third Party Data Feeds listed below (''Suspended Services'') is available until May 24, 2021 (''Transition Period''). During the Transition Period, the Exchange will not charge any fees for the Suspended Services. At the conclusion of the Transition Period, any remaining customers of Suspended Services will have their Suspended Services terminated.

Suspended Third Party Systems
Long Term Stock Exchange (LTSE)
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities
Morgan Stanley
TD Ameritrade

Suspended Third Party Data Feeds
ICE Data Services—ICE TMC
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities

(6) Proposal To Remove LCN Access—1 Gb Circuit

The Exchange proposes to delete the service ''LCN Access—1 Gb Circuit'' from the list of available types of services. The number of 1 Gb LCN ports purchased by Users has steadily declined from 4 in 2017, to 2 in 2018,

[6] *See* Securities Exchange Act Release No. 88980 (June 1, 2020), 85 FR 34697 (June 5, 2020) (SR–NYSEArca–2020–49).

[7] The Exchange first waived the Hot Hands Fee in a March 17, 2020 filing, and subsequently extended the waiver four times. *See* Securities Exchange Act Release Nos. 88398 (March 17, 2020), 85 FR 16398 (March 23, 2020) (SRNYSEArca–2020–22); 88520 (March 31, 2020), 85 FR 19208 (April 6, 2020) (SRNYSEArca–2020–26); 88961 (May 27, 2020), 85 FR 33755 (June 2, 2020) (SRNYSEArca–2020–47); 89174 (June 29, 2020), 85 FR 40349 (July 6, 2020) (SRNYSEArca–2020–58); and 89652 (August 25, 2020), 85 FR 53885 (August 31, 2020) (SR–NYSEArca–2020–74).

[8] *See* Securities Exchange Act Release No. 91388 (March 23, 2021), 86 FR 16433 (March 29, 2021) (NYSEArca–2021–15).

[9] *See* Securities Exchange Act Release No. 91790 (May 7, 2021) (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSECHX–2021–04, SR–NYSENAT–2021–05).

[10] *See* Securities Exchange Act Release No. 91861 (May 12, 2021) (SR–NYSEArca–2021–38).

to 1 in 2021, to zero currently. The Exchange understands that this fall-off in demand for the 1 Gb LCN port is due to the fact that market data feeds continue to increase in bandwidth, such that Users prefer to purchase larger port sizes. Indeed, the last remaining User with a 1 Gb LCN port discontinued that port in June 2022 and has switched to a 10 Gb LCN port instead. The Exchange believes that there is no remaining User demand for the 1 Gb LCN port, and accordingly, the Exchange proposes to discontinue the service as obsolete.

Application and Impact of the Proposed Changes

The Exchange does not expect that the proposed changes would have any impact. The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users [11] equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Fee Schedules are applied uniformly to all Users.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that updating the names of existing Third Party Services and Third Party Data Feeds and removing obsolete text from the Fee Schedules would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Updating the names of the Third Party Services and Third Party Data Feeds at issue will enhance the clarity and transparency of the Fee Schedules and reduce potential customer confusion. Removing obsolete references to (i) the GIF and its associated fee, (ii) the note regarding the Hot Hands service, and (iii) the availability of the Suspended Services would make it easier to read, understand, and administer the Fee Schedules, enhancing their clarity and transparency and alleviating possible customer confusion.

Similarly, the Exchange believes that discontinuing offering the 1 Gb LCN connection would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb LCN connection has declined in recent years and there are currently no Users that subscribe to the service. The Exchange does not expect demand to rebound given Users' overall preference for larger port sizes to accommodate larger market data feeds. Removing references to the fees for this obsolete service from the Price List would make the Price List easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would update obsolete product names, delete obsolete services, and remove obsolete text from the Fee Schedules, in order to enhance transparency and alleviate potential customer confusion.

The Exchange believes that updating the names of existing Third Party Systems and Third Party Data Feeds and removing obsolete text from the Fee Schedules would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the names of the existing systems and data feeds at issue would be updated and clarified in the Fee Schedules for all Users; the obsolete 1 Gb LCN connection would be removed for all Users; and obsolete text regarding the GIF, the note to the Hot Hands service, and the availability of the Suspended Services would be removed from the Fee Schedules as to all Users.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Fee Schedules and alleviate possible customer confusion that may arise from the inclusion of obsolete services and product names.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

[11] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedules, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(8).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2022–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2022–41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2022–41 and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16254 Filed 7–28–22; 8:45 am]

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[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95359; File No. SR–NYSEAMER–2022–31]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule

July 25, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 12, 2022, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule (together, the ''Price List and Fee Schedule'') related to colocation to remove obsolete text. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List and Fee Schedule related to colocation to remove obsolete text.[4]

(1) Proposal To Change Names of Select Third Party Systems and Third Party Data Feeds

As set forth in the Price List and Fee Schedule, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[5] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Price List and Fee Schedule.

The Exchange proposes to amend the list of Third Party Systems in the Price List and Fee Schedule to reflect the following updated names for existing Third Party Systems:

- Change the name of the ''Miami International Securities Exchange'' to ''MIAX Options,'' and
- Change the name of the ''MIAX PEARL'' to ''MIAX PEARL Options.''

The Exchange also proposes to amend the list of Third Party Data Feeds in the Price List and Fee Schedule to reflect the following updated names for existing Third Party Data Feeds:

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–30, SR–NYSEArca–2022–41, SR–NYSECHX–2022–17, and SR–NYSENAT–2022–12.

[5] *See* Securities Exchange Act Release No. 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (NYSEMKT–2016–63).

• Change the name ''Miami International Securities Exchange/MIAX PEARL'' to ''MIAX Options/MIAX PEARL Options;'' and

• Change ''SR Labs—SuperFeed'' data feeds to ''Vela—SuperFeed,'' to reflect the content provider's recent change to the name of these products.

This change would update the names of these services, but would not make any change to the services provided.

(2) Proposal To Delete Discontinued Third Party Data Feed

The Exchange proposes to delete the ''NASDAQ OMDF'' data feed from the list of available Third Party Data Feeds, as it is no longer offered by the content service provider.

(3) Proposal To Remove References to ICE Data Global Index

The Exchange proposes to remove obsolete references to the ICE Data Global Index (the ''GIF'') from the list of Third Party Data Feeds available for connectivity and related text.

In May 2020, ICE, which publishes the GIF, announced to its customers that before the end of 2020, it would cease offering the GIF as a stand-alone product. The Exchange accordingly amended the Price List and Fee Schedule to inform customers that it would cease offering connectivity to the GIF once it is no longer available.[6]

ICE has informed the Exchange that it ceased offering the GIF as a stand-alone product, making the references to the GIF obsolete. The operative date was announced through a customer notice. Accordingly, the Exchange proposes to remove ''ICE Data Global Index *'' and the corresponding asterisked note from the Price List and Fee Schedule.

In order to implement the proposed change, the Exchange proposes to make the following changes to the sections of the Price List and Fee Schedule entitled ''Connectivity to Third Party Data Feeds'':

• In the first paragraph and in the table of Third Party Data Feeds, delete ''ICE Data Global Index *''.

• Following the table of Third Party Data Feeds, delete the following text:

** ICE will cease to offer the GIF as a stand-alone product, which the Exchange has been informed by ICE is currently expected to occur before the end of 2020. The Exchange will announce the operative date through a customer notice. Any change fees that a User would otherwise incur as a result of the proposed change will be waived.*

(4) Proposal To Remove the Temporary Waiver of Hot Hands Fees

The Exchange proposes to remove the obsolete reference to the waiver of Hot Hands fees in light of the reopening of the data center in Mahwah, New Jersey (''Mahwah Data Center'' or ''MDC'').

In March 2020, ICE announced to each User that, starting on March 16, 2020, the MDC would be closed to third parties in response to COVID–19. The Exchange temporarily waived all Hot Hands fees from the date of the closing through the date of the reopening of the MDC, and added a note to the fees for the Hot Hands service stating as much.[7]

The MDC reopened on October 1, 2020. The date of the reopening was announced through a customer notice. As a result of the reopening, the waiver of Hot Hands fees ceased, and the note became obsolete. The Exchange now proposes to remove the obsolete text.

In order to implement this proposed change, the Exchange proposes to make the following changes to the Price List and Fee Schedule:

• In the Types of Service table, remove the ''†'' symbol after ''Hot Hands Service ***''.

• Following the Types of Service table, remove the following text:

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the reopening of the Mahwah, New Jersey data center. The date of the reopening will be announced through a customer notice.

(5) Proposal To Remove Obsolete Text About Transition Period for Suspended Services

The Exchange proposes to remove obsolete text regarding the transition period that expired on May 24, 2021 concerning the Exchange's provision of suspended services at no charge.

As background, on March 10, 2021, the Exchange filed with the Commission a proposed rule change for immediate effectiveness that amended the colocation services offered by the Exchange to provide Users the option to access the systems and data feeds of various additional third parties.[8] The proposed rule change became operative on April 9, 2021, and five Users subsequently contracted to receive the services that were added in the filing.

On May 7, 2021, the Commission suspended the filing and instituted proceedings to determine whether the proposed rule change should be approved or disapproved.[9] Such action suspended the Exchange's ability to offer access to Third Party Systems from Long Term Stock Exchange, Members Exchange, MIAX Emerald, MIAX PEARL Equities, Morgan Stanley, and TD Ameritrade, and to offer connectivity to Third Party Data Feeds from ICE Data Services—ICE TMC, Members Exchange, MIAX Emerald, and MIAX PEARL Equities (together, the ''Suspended Services'').

On May 12, 2021, the Commission approved for immediate effectiveness the Exchange's filing proposing to provide the Suspended Services to all Users, at no charge, for a period of 14 days (''Transition Period'') through May 24, 2021, to enable current Users to maintain their connectivity while establishing alternate connectivity.[10]

Given that the Transition Period has expired, the Exchange proposes to remove the obsolete text regarding this provision. To that end, the Exchange proposes to delete the following text:

Connectivity to Suspended Third Party Systems and Suspended Third Party Data Feeds

Connectivity to the Third Party Systems and Third Party Data Feeds listed below (''Suspended Services'') is available until May 24, 2021 (''Transition Period''). During the Transition Period, the Exchange will not charge any fees for the Suspended Services. At the conclusion of the Transition Period, any remaining customers of Suspended Services will have their Suspended Services terminated.

Suspended Third Party Systems
Long Term Stock Exchange (LTSE)
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities
Morgan Stanley
TD Ameritrade

Suspended Third Party Data Feeds
ICE Data Services—ICE TMC
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities

(6) Proposal To Remove LCN Access—1 Gb Circuit

The Exchange proposes to delete the service ''LCN Access—1 Gb Circuit''

[6] *See* Securities Exchange Act Release No. 88979 (June 1, 2020), 85 FR 34663 (June 5, 2020) (SR–NYSEAMER–2020–40).

[7] The Exchange first waived the Hot Hands Fee in a March 17, 2020 filing, and subsequently extended the waiver four times. *See* Securities Exchange Act Release Nos. 88403 (March 17, 2020), 85 FR 16400 (March 23, 2020) (SRNYSEAMER–2020–19); 88523 (March 31, 2020), 85 FR 19179 (April 6, 2020) (SR–NYSEAMER–2020–23); 88956 (May 27, 2020), 85 FR 33760 (June 2, 2020) (SR–NYSEAMER–2020–39); 89173 (June 29, 2020), 85 FR 40352 (July 6, 2020) (SR–NYSEAMER–2020–46); and 89651 (August 25, 2020), 85 FR 53896 (August 31, 2020) (SR–NYSEAMER–2020–63).

[8] *See* Securities Exchange Act Release No. 91387 (March 23, 2021), 86 FR 16417 (March 29, 2021) (NYSEAMER–2021–2021–13).

[9] *See* Securities Exchange Act Release No. 91790 (May 7, 2021) (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSECHX–2021–04, SR–NYSENAT–2021–05).

[10] *See* Securities Exchange Act Release No. 91860 (May 12, 2021) (SR–NYSEAMER–2021–26).

from the list of available types of services. The number of 1 Gb LCN ports purchased by Users has steadily declined from 4 in 2017, to 2 in 2018, to 1 in 2021, to zero currently. The Exchange understands that this fall-off in demand for the 1 Gb LCN port is due to the fact that market data feeds continue to increase in bandwidth, such that Users prefer to purchase larger port sizes. Indeed, the last remaining User with a 1 Gb LCN port discontinued that port in June 2022 and has switched to a 10 Gb LCN port instead. The Exchange believes that there is no remaining User demand for the 1 Gb LCN port, and accordingly, the Exchange proposes to discontinue the service as obsolete.

Application and Impact of the Proposed Changes

The Exchange does not expect that the proposed changes would have any impact. The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users [11] equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Price List and Fee Schedule are applied uniformly to all Users.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that updating the names of existing Third Party Services and Third Party Data Feeds and removing obsolete text from the Price List and Fee Schedule would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Updating the names of the Third Party Services and Third Party Data Feeds at issue will enhance the clarity and transparency of the Price List and Fee Schedule and reduce potential customer confusion. Removing obsolete references to (i) the GIF and its associated fee, (ii) the note regarding the Hot Hands service, and (iii) the availability of the Suspended Services would make it easier to read, understand, and administer the Price List and Fee Schedule, enhancing their clarity and transparency and alleviating possible customer confusion.

Similarly, the Exchange believes that discontinuing offering the 1 Gb LCN connection would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb LCN connection has declined in recent years and there are currently no Users that subscribe to the service. The Exchange does not expect demand to rebound given Users' overall preference for larger port sizes to accommodate larger market data feeds. Removing references to the fees for this obsolete service from the Price List would make the Price List easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would update obsolete product names, delete obsolete services, and remove obsolete text from the Price List and Fee Schedule, in order to enhance transparency and alleviate potential customer confusion.

The Exchange believes that updating the names of existing Third Party Systems and Third Party Data Feeds and removing obsolete text from the Price List and Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the names of the existing systems and data feeds at issue would be updated and clarified in the Price List and Fee Schedule for all Users; the obsolete 1 Gb LCN connection would be removed for all Users; and obsolete text regarding the GIF, the note to the Hot Hands service, and the availability of the Suspended Services would be removed from the Price List and Fee Schedule as to all Users.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Price List and Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services and product names.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

[11] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Price List and Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(8).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2022–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–31 and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16253 Filed 7–28–22; 8:45 am]

BILLING CODE 8011–01–P

Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95358; File No. SR–NYSE–2022–30]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List Related to Colocation

July 25, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 12, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List related to colocation to remove obsolete text. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List related to colocation to remove obsolete text.[4]

(1) Proposal To Change Names of Select Third Party Systems and Third Party Data Feeds

As set forth in the Price List, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[5] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Price List.

The Exchange proposes to amend the list of Third Party Systems in the Price List to reflect the following updated names for existing Third Party Systems:

- Change the name of the ''Miami International Securities Exchange'' to ''MIAX Options,'' and
- Change the name of the ''MIAX PEARL'' to ''MIAX PEARL Options.''

The Exchange also proposes to amend the list of Third Party Data Feeds in the Price List to reflect the following updated names for existing Third Party Data Feeds:

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–SR–NYSEAMER–2022–31, SR–NYSEArca–2022–41, SR–NYSECHX–2022–17, and SR–NYSENAT–2022–12.

[5] *See* Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR–NYSE–2016–45).

• Change the name ''Miami International Securities Exchange/MIAX PEARL'' to ''MIAX Options/MIAX PEARL Options;'' and

• Change ''SR Labs—SuperFeed'' data feeds to ''Vela—SuperFeed,'' to reflect the content provider's recent change to the name of these products.

This change would update the names of these services, but would not make any change to the services provided.

(2) Proposal To Delete Discontinued Third Party Data Feed

The Exchange proposes to delete the ''NASDAQ OMDF'' data feed from the list of available Third Party Data Feeds, as it is no longer offered by the content service provider.

(3) Proposal To Remove References to ICE Data Global Index

The Exchange proposes to remove obsolete references to the ICE Data Global Index (the ''GIF'') from the list of Third Party Data Feeds available for connectivity and related text.

In May 2020, ICE, which publishes the GIF, announced to its customers that before the end of 2020, it would cease offering the GIF as a stand-alone product. The Exchange accordingly amended its Price List to inform customers that it would cease offering connectivity to the GIF once it is no longer available.[6]

ICE has informed the Exchange that it ceased offering the GIF as a stand-alone product, making the references to the GIF obsolete. The operative date was announced through a customer notice. Accordingly, the Exchange proposes to remove ''ICE Data Global Index *'' and the corresponding asterisked note from the Price List.

In order to implement the proposed change, the Exchange proposes to make the following changes to the section of the Price List entitled ''Connectivity to Third Party Data Feeds'':

• In the first paragraph and in the table of Third Party Data Feeds, delete ''ICE Data Global Index *''.

• Following the table of Third Party Data Feeds, delete the following text:

** ICE will cease to offer the GIF as a stand-alone product, which the Exchange has been informed by ICE is currently expected to occur before the end of 2020. The Exchange will announce the operative date through a customer notice. Any change fees that a User would otherwise incur as a result of the proposed change will be waived.*

(4) Proposal To Remove the Temporary Waiver of Hot Hands Fees

The Exchange proposes to remove the obsolete reference to the waiver of Hot Hands fees in light of the reopening of the data center in Mahwah, New Jersey (''Mahwah Data Center'' or ''MDC'').

In March 2020, ICE announced to each User that, starting on March 16, 2020, the MDC would be closed to third parties in response to COVID–19. The Exchange temporarily waived all Hot Hands fees from the date of the closing through the date of the reopening of the MDC, and added a note to the fees for the Hot Hands service stating as much.[7]

The MDC reopened on October 1, 2020. The date of the reopening was announced through a customer notice. As a result of the reopening, the waiver of Hot Hands fees ceased, and the note became obsolete. The Exchange now proposes to remove the obsolete text.

In order to implement this proposed change, the Exchange proposes to make the following changes to the Price List:

• In the Types of Service table, remove the ''†'' symbol after ''Hot Hands Service ***''.

• Following the Types of Service table, remove the following text:

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the reopening of the Mahwah, New Jersey data center. The date of the reopening will be announced through a customer notice.

(5) Proposal To Remove Obsolete Text About Transition Period for Suspended Services

The Exchange proposes to remove obsolete text regarding the transition period that expired on May 24, 2021 concerning the Exchange's provision of suspended services at no charge.

As background, on March 10, 2021, the Exchange filed with the Commission a proposed rule change for immediate effectiveness that amended the colocation services offered by the Exchange to provide Users the option to access the systems and data feeds of various additional third parties.[8] The proposed rule change became operative on April 9, 2021, and five Users subsequently contracted to receive the services that were added in the filing.

On May 7, 2021, the Commission suspended the filing and instituted proceedings to determine whether the proposed rule change should be approved or disapproved.[9] Such action suspended the Exchange's ability to offer access to Third Party Systems from Long Term Stock Exchange, Members Exchange, MIAX Emerald, MIAX PEARL Equities, Morgan Stanley, and TD Ameritrade, and to offer connectivity to Third Party Data Feeds from ICE Data Services—ICE TMC, Members Exchange, MIAX Emerald, and MIAX PEARL Equities (together, the ''Suspended Services'').

On May 12, 2021, the Commission approved for immediate effectiveness the Exchange's filing proposing to provide the Suspended Services to all Users, at no charge, for a period of 14 days (''Transition Period'') through May 24, 2021, to enable current Users to maintain their connectivity while establishing alternate connectivity.[10]

Given that the Transition Period has expired, the Exchange proposes to remove the obsolete text regarding this provision. To that end, the Exchange proposes to delete the following text:

Connectivity to Suspended Third Party Systems and Suspended Third Party Data Feeds

Connectivity to the Third Party Systems and Third Party Data Feeds listed below (''Suspended Services'') is available until May 24, 2021 (''Transition Period''). During the Transition Period, the Exchange will not charge any fees for the Suspended Services. At the conclusion of the Transition Period, any remaining customers of Suspended Services will have their Suspended Services terminated.

Suspended Third Party Systems
Long Term Stock Exchange (LTSE)
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities
Morgan Stanley
TD Ameritrade

Suspended Third Party Data Feeds
ICE Data Services—ICE TMC
Members Exchange (MEMX)
MIAX Emerald
MIAX PEARL Equities

(6) Proposal To Remove LCN Access—1 Gb Circuit

The Exchange proposes to delete the service ''LCN Access—1 Gb Circuit'' from the list of available types of

[6] *See* Securities Exchange Act Release No. 88985 (June 1, 2020), 85 FR 34666 (June 5, 2020) (SR–NYSE–2020–46).

[7] The Exchange first waived the Hot Hands Fee in a March 17, 2020 filing, and subsequently extended the waiver four times. *See* Securities Exchange Act Release Nos. 88397 (March 17, 2020), 85 FR 16406 (March 23, 2020) (SR–NYSE–2020–18); 88518 (March 31, 2020), 85 FR 19187 (April 6, 2020) (SR–NYSE–2020–25); 88955 (May 27, 2020), 85 FR 33758 (June 2, 2020) (SR–NYSE–2020–44); 89172 (June 29, 2020), 85 FR 40347 (July 6, 2020) (SR–NYSE–2020–53); and 89655 (August 25, 2020), 85 FR 53872 (August 31, 2020) (SR–NYSE–2020–69).

[8] *See* Securities Exchange Act Release No. 91386 (March 23, 2021), 86 FR 16410 (March 29, 2021) (SR–NYSE–2021–15).

[9] *See* Securities Exchange Act Release No. 91790 (May 7, 2021) (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSECHX–2021–04, SR–NYSENAT–2021–05).

[10] *See* Securities Exchange Act Release No. 91859 (May 12, 2021) (SR–NYSE–2021–31).

services. The number of 1 Gb LCN ports purchased by Users has steadily declined from 4 in 2017, to 2 in 2018, to 1 in 2021, to zero currently. The Exchange understands that this fall-off in demand for the 1 Gb LCN port is due to the fact that market data feeds continue to increase in bandwidth, such that Users prefer to purchase larger port sizes. Indeed, the last remaining User with a 1 Gb LCN port discontinued that port in June 2022 and has switched to a 10 Gb LCN port instead. The Exchange believes that there is no remaining User demand for the 1 Gb LCN port, and accordingly, the Exchange proposes to discontinue the service as obsolete.

Application and Impact of the Proposed Changes

The Exchange does not expect that the proposed changes would have any impact. The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users [11] equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Price List is applied uniformly to all Users.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that updating the names of existing Third Party Services and Third Party Data Feeds and removing obsolete text from the Price List would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Updating the names of the Third Party Services and Third Party Data Feeds at issue will enhance the clarity and transparency of the Price List and reduce potential customer confusion. Removing obsolete references to (i) the GIF and its associated fee, (ii) the note regarding the Hot Hands service, and (iii) the availability of the Suspended Services would make it easier to read, understand, and administer the Price List, enhancing its clarity and transparency and alleviating possible customer confusion.

Similarly, the Exchange believes that discontinuing offering the 1 Gb LCN connection would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb LCN connection has declined in recent years and there are currently no Users that subscribe to the service. The Exchange does not expect demand to rebound given Users' overall preference for larger port sizes to accommodate larger market data feeds. Removing references to the fees for this obsolete service from the Price List would make the Price List easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would update obsolete product names, delete obsolete services, and remove obsolete text from the Price List, in order to enhance transparency and alleviate potential customer confusion.

The Exchange believes that updating the names of existing Third Party Systems and Third Party Data Feeds and removing obsolete text from the Price List would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the names of the existing systems and data feeds at issue would be updated and clarified in the Price List for all Users; the obsolete 1 Gb LCN connection would be removed for all Users; and obsolete text regarding the GIF, the note to the Hot Hands service, and the availability of the Suspended Services would be removed from the Price List as to all Users.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Price List and alleviate possible customer confusion that may arise from the inclusion of obsolete services and product names.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

[11] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(8).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as

Continued

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–30 and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

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designated by the Commission. The Exchange has satisfied this requirement.

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95357; File No. SR–ICC–2022–012]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the Clearing Rules

July 25, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 19, 2022, ICE Clear Credit LLC (''ICE Clear Credit'' or ''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to implement certain amendments to ICC's Clearing Rules (the ''Rules'') to permit it to take advantage of certain additional settlement finality protections under applicable UK and EU law. The text of the proposed amendments is attached in Exhibit 5 [sic].

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

The purpose of the proposed changes is to modify certain provisions of the Rules to permit the clearing house to take advantage of certain protections for default rights and remedies under applicable United Kingdom (''UK'') and European Union (''EU'') Settlement Finality Laws and regulations. The amendments are expected to be principally relevant in the case of an insolvency of an ICC clearing participant (''Participant'') domiciled in the UK or an EU member state. The amendments would rely on certain protections in such Settlement Finality Laws and regulations that provide additional support (on top of existing protections in applicable law) for the enforceability of the clearing house's default rights and remedies under the Rules without interference in such an insolvency.

By way of background, the EU Settlement Finality Directive [3] introduced various insolvency-related protections in relation to ''designated systems'' used by EU participants to transfer financial instruments and payments, and participation in those systems. The Settlement Finality Directive aims to ensure that as a matter of EU member state laws, transfer orders which enter into such systems are finally settled, regardless of whether the sending participant has gone into an insolvency process. Transfer orders for this purpose include instructions to make cash payments (including margin payments) and instructions to transfer securities (including as margin or in physical settlement of a cleared transaction, if applicable). Under the Settlement Finality Directive, transfer orders and related netting arrangements

[3] EU Directive 98/26/EC.

are enforceable, even in the event of insolvency proceedings against a participant, provided that the transfer order was entered into the system before the opening of the insolvency proceeding.[4] Further, under the Settlement Finality Directive, the right of the operator of a designated system to realize and apply collateral security provided by a participant would not be affected by insolvency proceedings against the participant.[5]

''Designated systems'' are defined as formal arrangements between three or more participants with common rules and standard arrangements for clearing or execution of transfer orders between participants which are governed by the law of an EU member state and have been designated as a system and notified to the European Securities and Markets Authority (''ESMA'').[6] Although the Settlement Finality Directive itself does not establish an equivalent regime for systems operated under the laws of a non-EU member state (''third-country systems''), such as United States (''US'') clearing houses, Recital 7 of the Settlement Finality Directive provides that member states may choose to apply the provisions of the Settlement Finality Directive to their domestic institutions which participate directly in third country systems and to collateral security provided in connection with participation in such systems. As a result, in some EU member states it is possible for a third country system such as ICE Clear Credit to receive national designation or be otherwise protected as a designated system for the purposes of that member state's national law.

The UK has implemented similar settlement finality regulations that continue to apply following the withdrawal of the UK from the EU, and which are also potentially applicable to UK institutions that participate in third country systems (such as a US clearing house).[7]

As discussed in further detail herein, ICE Clear Credit is proposing to adopt amendments to its Rules to introduce explicit provisions relating to the settlement finality of transfer orders, in order to take advantage of the protections of Settlement Finality Laws. Specifically, the amendments would address which ''transfer orders'' arise in its system, when they become irrevocable, who is bound by them and when they terminate. ICE Clear Credit believes that the amendments would facilitate obtaining the relevant protections of the Settlement Finality Directive and UK Settlement Finality Regulations, which will principally be relevant in the case of an insolvency of a Participant that is domiciled in an EU member state or in the UK. The amendments would not otherwise affect the clearing house's rights and obligations under the Rules, including default rights and remedies, and would not be expected to be relevant to an insolvency proceeding involving a Participant organized in the US or otherwise outside of the EU or the UK. ICC proposes to move forward with implementation of these changes following Commission approval of the proposed rule change.

ICE Clear Credit would adopt a new Part 10 of the Rules addressing Settlement Finality Laws. Rule 1000 would add a number of related definitions, including definitions for relevant legislation and regulations, such as ''EMIR,'' ''Financial Collateral Directive,'' ''Financial Collateral Regulations,'' ''FSMA,'' ''Settlement Finality Directive,'' ''Settlement Finality Regulations'' and ''UK EMIR.'' The rule would also adopt key definitions relating to the settlement finality provisions, including ''ICE Systems'' (referencing ICE Clear Credit's trade registration, clearing processing and finance systems), ''SFD System'' (referencing the third country system operated by ICE Clear Credit for purposes of the Settlement Finality Laws), ''Payment Transfer Order,'' ''Securities Transfer Order'' and ''Transfer Order'' (representing the types of transfer orders used in the ICE system and covered by the Settlement Finality Laws), ''SFD Participant'' (referencing ICE Clear Credit itself, its Participants organized in the European Economic Area (''EEA'') or in the UK, among certain other relevant persons), ''SFD Custodian'' (referencing a custodian located in the EEA or the UK used by ICE Clear Credit or a Participant for the holding or transfer of Non-Cash Collateral), ''SFD Financial Institution'' (referencing a financial institution located in the EEA or UK used by ICE Clear Credit or a Participant for purpose of the deposit or transfer of cash), ''SFD Security'' (referencing a security as defined in the Settlement Finality Laws), ''Indirect Participant'' (referencing Non-Participant Parties that fall within the definition of indirect participant under the Settlement Finality Laws), and ''Non-Cash Collateral'' (referencing Margin or Collateral in the form of a security).

New Rule 1001 would set out general principles relevant to implementation of the EU and UK settlement finality arrangements. Subsection (a) would provide that ICC is the operator of a third country system for purposes of relevant Settlement Finality Laws, and that Chapter 10 of the Rules would apply to ICE Clear Credit and SFD Participants to the extent that the Settlement Finality Laws are applicable to such persons. Subsection (b) would require SFD Participants to comply with actions taken by ICC pursuant to Chapter 10 and the relevant Settlement Finality Laws, and to acknowledge that the Settlement Finality Laws modify certain otherwise applicable provisions of insolvency laws. Subsection (c) would provide that each SFD Participant is on notice of the provisions of Chapter 10, and by virtue of participating in the SFD System, is deemed to agree to the application of Chapter 10 (including in the event of any conflict with any other agreement or obligation). Subsection (d) would provide an additional acknowledgment that Margin and Collateral transferred to ICC under the Rules fall within certain protections for collateral arrangements under the Settlement Finality Laws.

New Rule 1002 would address the timing and circumstances in which various types of Transfer Orders would arise for purposes of the ICC SFD System, specifically Payment Transfer Orders and Securities Transfer Orders in various circumstances, including for transfer of positions (''Position Transfer Orders''), transfer of non-cash collateral (''Collateral Transfer Orders''), submission of new trades for clearing (''New Transaction Clearing Orders''), backloading trades for clearing (''Backloaded Transaction Clearing Orders, and together with New Transaction Clearing Orders, ''Transaction Clearing Orders''), and physical settlement under cleared CDS contracts (''CDS Physical Settlement Orders''). The rule would also specify the subject matter of each type of Transfer Order (*e.g.,* a payment in respect of a Payment Transfer Order) and the parties in respect of which each type of Transfer Order would apply and have effect (*e.g.,* in the case of a Payment Transfer Order, the affected Participant (if it is an SFD Participant), ICE Clear Credit, and any affected SFD Financial Institution). Rule 1002 would also address the possibility of multiple Transfer Orders existing in respect of the same obligation (which may exist, but would not result in the duplication

[4] Settlement Finality Directive Article 3(1).

[5] Settlement Finality Directive Article 9.

[6] Settlement Finality Directive Article 2(a).

[7] Financial Markets and Insolvency (Settlement Finality) Regulations 1999.

As used herein, the EU Settlement Finality Directive, national implementing legislation and the UK Settlement Finality Regulations are collectively referred to as ''Settlement Finality Laws.''

of any obligation), and the fact that netting or close out of Contracts would not affect the status of Transfer Orders. The rule also states, consistent with the general approach of the Rules, that where a Transfer Order applies to an Indirect Participant, it would not affect the liability of any SFD Participant pursuant to the same Transfer Order.

Rule 1003 would specify the time at which each type of Transfer Order (specifically, Payment Transfer Orders, Position Transfer Orders, Collateral Transfer Orders, Transaction Clearing Orders and CDS Physical Settlement Orders) becomes irrevocable for purposes of the relevant Settlement Finality Laws. Payment Transfer Orders would become irrevocable at the earlier of the time payment is received or at the time the relevant financial institution used by ICC for this purpose sends a SWIFT or other confirmation that payment has been made. Collateral Transfer Orders similarly would become irrevocable at the earlier of the time the transfer is received or a related securities transfer order in a relevant securities transfer system becomes irrevocable. Position Transfer Orders would become irrevocable at the time the position transfer is recorded in the ICC systems, and Transaction Clearing Orders would become irrevocable at the applicable Novation Time under the Rules. CDS Physical Settlement Orders would become irrevocable at the earliest of (1) the time the Matched Delivery Buyer has irrevocably instructed its custodian to transfer the relevant securities to the Matched Delivery Seller, (2) the time the relevant instrument is delivered or assigned, or (3) the time notice is otherwise given under the Rules that the Matched Delivery Pair have settled the relevant Matched Delivery Contracts. Under the Rule, as from the time when the Transfer Order becomes irrevocable, it cannot be revoked or purported to be revoked by any SFD Participant or ICE Clear Credit and will be binding on all SFD Participants.

Rule 1004 would address variations or cancellations of Transfers Orders prior to the time they become irrevocable, in specified circumstances. These circumstances include, for any Transfer Order, cases where the order is affected by manifest or proven error or an error agreed by all affected SFD Participants. Additional grounds for variation or cancellation apply for particular types of Transfer Order, including, in the case of a Payment Transfer Order or Collateral Transfer Order, where the underlying Contract is void or avoided under the Rules or appliable law, or amended as a result of ICC exercising its discretion under the Rules. Transaction Clearing Orders may be subject to variation or cancellation where the underlying trade is not eligible for clearing or otherwise not accepted for clearing, and Backloaded Transaction Clearing Orders may be subject to variation or cancellation if an error or omission is noted to ICC prior to the Novation Time. Similarly, variation or cancellation of a CDS Physical Settlement Order may be made if a NOPS Amendment Notice is validly delivered under the Rules or ICE Clear Credit Procedures. Under Rule 1004, in these circumstances, ICC would be permitted to make appropriate modifications to the relevant Transfer Order, or in the alternative to cancel the relevant Transfer Order. Rule 1004 also would not preclude ICC from taking steps to give rise to a new Transfer Order with opposite effect to an existing Transfer Order or part thereof. Rule 1004 also would provide for notice of any modification or cancellation of a Transfer Order to affected SFD Participants.

Rule 1005 would specify the circumstances under which Transfer Orders are deemed satisfied. Specifically, Payment Transfer Orders are satisfied upon all required payments being received in immediately available funds or full satisfaction of the underlying obligation is otherwise made and recorded in ICC's systems, free of any encumbrances. Position Transfer Orders would be deemed satisfied upon becoming irrevocable (at which time the relevant positions have been transferred under the Rules). Collateral Transfer Orders would be deemed satisfied upon ICC or the Participant, as applicable, receiving the Non-Cash Collateral in its account or upon the definitive record of the assets transferred by the Participant being updated to reflect the successful transfer of the relevant collateral. Transaction Clearing Orders would be deemed satisfied at the time the relevant cleared contracts arise under the Rules. A CDS Physical Settlement Order would be deemed satisfied at the time ICC updates its records to reflect that physical delivery of the relevant security has been completed or the delivery obligations of the parties are otherwise discharged or settled.

Rule 1006 would set out certain acknowledgements of ICC, Participants and Non-Participant Parties with respect to matters relating to Margin or Collateral to the extent they fall to be determined under the laws of an EEA member state or the UK. The amendments would clarify that such arrangements are subject to the EU Financial Collateral Directive or UK Financial Collateral Regulations, as applicable, and would provide that Participants and Non-Participant Parties would not dispute that characterization. The amendments would further provide that arrangements for the provision of cash Margin and Collateral constitute ''title transfer financial collateral arrangements'' and arrangements for the provision of Pledged Items constitute ''security financial collateral arrangements'', in each case for purposes of the EU Financial Collateral Directive or UK Financial Collateral Arrangements, that all such Margin and Collateral constitute ''financial collateral'' for purposes of such laws, and that ICC has possession or control of such Margin and Collateral for purposes of such laws. The amendments would also state that for purposes of UK law, the security arrangements under the Rules constitute a ''market charge'' for purposes of the Companies Act 1989, which provides certain protections for the enforceability of such arrangements in the event of the insolvency of a clearing participant.

ICC also proposes to make certain amendments to Rule 611, which currently addresses the treatment of certain Rules under various insolvency laws and other protections for the enforceability of default remedies in the event of the insolvency of a clearing participant. The amendments would add a new subsection (f), which would provide that specified Rules providing for default rights and remedies would constitute default rules, procedures and similar arrangements as defined for purposes of relevant EU and UK law, including EMIR, UK EMIR, and the Settlement Finality Laws.

(b) Statutory Basis

ICE Clear Credit believes that the proposed amendments are consistent with the requirements of Section 17A of the Act[8] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[9] Section 17A(b)(3)(F) of the Act[10] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

[8] 15 U.S.C. 78q–1.

[9] 17 CFR 240.17Ad–22.

[10] 15 U.S.C. 78q–1(b)(3)(F).

The amendments are intended to permit the clearing house explicitly to take advantage of certain additional protections for the enforceability of default rights and remedies that may be available under EU and UK law, principally in the context of the insolvency of a Participant domiciled in the EU or the UK. The amendments would not themselves change any of the existing default rights or remedies of ICC. Rather, the amendments adopt explicit provisions relating to settlement finality of transfer orders relating to various clearing activities, most importantly the payment and transfer of Margin and Collateral, and the enforcement of ICC's rights with respect thereto, in order to facilitate potential reliance by the clearing house on settlement finality protections existing under relevant Settlement Finality Laws. The amendments would thus provide additional legal certainty as to the ability of the clearing house to enforce its default rights and remedies (including its rights to use Margin and Collateral provided by Participants under the Rules) in the event of the insolvency of a Participant domiciled in the EU or the UK (on top of existing protections for the enforceability of such rights and remedies on which the clearing house may currently rely). As such, the amendments are, in ICC's view, consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of the investors and the public interest, within the meaning of Section 17A(b)(3)(F).[11]

Moreover, the amendments are consistent with relevant provisions of Rule 17Ad–22.[12] In particular, Rule 17Ad–22(e)(1) requires that each covered clearing agency ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . provide for a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.'' [13] As discussed above, the amendments would provide an additional legal basis to support the enforceability of the clearing house's default rules in the context of an insolvency of a Participant that is domiciled in an EU member state or in the UK. The amendments would in particular facilitate the clearing house's taking advantage of protections for the enforceability of transfer orders, including in default scenarios, based on the EU Settlement Finality Directive and UK Settlement Finality Regulations. The amendments thus enhance the legal certainty of the framework supporting ICC's activities in those jurisdictions. As a result, ICC believes the amendments are consistent with the requirements of Rule 17Ad–22(e)(1).[14]

Rule 17Ad–22(e)(13) requires that each covered clearing agency ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . ensure the covered clearing agency has the authority and operational capacity to take timely action to contain losses and liquidity demands and continue to meet its obligations . . .'' [15] As discussed herein, ICC is not proposing to change the substance of its existing default remedies and procedures under the Rules and the ICE Clear Credit Procedures. The amendments to the Rules are intended to enhance the legal certainty of those existing default remedies and procedures in the context of an insolvency of a clearing participant domiciled in the EU or the UK by facilitating the clearing house's ability to take advantage of protections for transfer orders under applicable Settlement Finality Laws. As such, in ICC view, the amendments will further compliance with the requirements of Rule 17Ad–22(e)(13).[16]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Credit does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments will not change the substantive default rights and remedies under the Rules, and so will not affect the rights or obligations of ICC itself or those of Participants. The changes are intended to enhance the legal certainty of existing clearing house default rights and remedies in the context of the insolvency of a Participant domiciled in the UK or EU, and thereby enhance the overall clearing framework. As a result, ICE Clear Credit does not believe the amendments will impact competition among clearing members or other market participants, adversely affect the ability of market participants to access clearing generally, or adversely affect the cost of clearing. ICE Clear Credit thus does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Credit. ICE Clear Credit will notify the Commission of any comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2022–012 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2022–012. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent

[11] 15 U.S.C. 78q–1(b)(3)(F).

[12] 17 CFR 240.17Ad–22.

[13] 17 CFR 240.17Ad–22(e)(1).

[14] 17 CFR 240.17Ad–22(e)(1).

[15] 17 CFR 240.17Ad–22(e)(13).

[16] 17 CFR 240.17Ad–22(e)(13).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2022–012 and should be submitted on or before August 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16251 Filed 7–28–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

National Women's Business Council; Notice of Public Meeting

AGENCY: Small Business Administration, National Women's Business Council.

ACTION: Notice of open public meeting.

DATES: The public meeting will be held on Wednesday, September 14, 2022, from 12:30 p.m. to 2:30 p.m. EDT.

ADDRESSES: This meeting is virtual and will be held via Zoom, a web conferencing platform. The access link will be provided to attendees upon registration.

FOR FURTHER INFORMATION CONTACT: For more information, please visit the NWBC website at *www.nwbc.gov,* email *info@nwbc.gov* or call 202–941–6001.

The meeting is open to the public; however, advance notice of attendance is requested. To RSVP, please visit the NWBC website at *www.nwbc.gov.* The ''2022 Public Meetings'' section will feature a link to register on Eventbrite.

NWBC strongly encourages that public comments and questions be submitted in advance by September 6th. The Eventbrite registration page will include an opportunity to do so, but individuals may also email *info@nwbc.gov* with subject line—''[Name/Organization] Comment for 09/14/22 Public Meeting.'' NWBC staff will read the first five submitted statements during the final 20 minutes of the program.

During the live event, attendees will be in listen-only mode and may submit additional questions via the Q&A Chat feature. For technical assistance, please visit the Zoom Support Page. All public comments will be included in the meeting record, which will be made available on *www.nwbc.gov* under the ''2022 Public Meetings'' section.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, the National Women's Business Council (NWBC) announces its third public meeting of Fiscal Year 2022. The 1988 Women's Business Ownership Act established NWBC to serve as an independent source of advice and policy recommendations to the President, Congress, and the Administrator of the U.S. Small Business Administration (SBA) on issues of importance to women entrepreneurs.

This meeting will allow the Council to recap its activity and engagement over the course of Fiscal Year 2022. Each of the Council's three subcommittees (Access to Capital & Opportunity, Women in STEM, and Rural Women's Entrepreneurship) will present their policy recommendations to the full body for deliberation and vote.

Dated: July 25, 2022.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2022–16249 Filed 7–28–22; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Investment Capital Advisory Committee

AGENCY: Small Business Administration (SBA).

ACTION: Notice of the establishment of the Investment Capital Advisory Committee.

SUMMARY: The SBA announces the establishment of the Investment Capital Advisory Committee. The Administrator has determined that establishing the Investment Capital Advisory Committee is necessary and in the public interest.

DATES: The Investment Capital Advisory Committee will operate for two years after the filing date of its charter that will meet the 15-days requirements of the **Federal Register** Notice, unless otherwise renewed in accordance with FACA.

FOR FURTHER INFORMATION CONTACT: Investment Capital Advisory Committee Designated Federal Officer, Jennifer Shieh, Director of Ecosystem Development, Office of Investment and Innovation, *ICAC@sba.gov.*

SUPPLEMENTARY INFORMATION: This notice announces the establishment of the Investment Capital Advisory Committee as a Federal Advisory Committee in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. app. 2) to provide information, advice, and recommendations to the Administrator on matters broadly related to facilitating greater access and availability of patient investment capital for small business; promoting greater awareness of SBA investment and innovation division programs and services; cultivating greater public-private engagement, cooperation, and collaboration; developing and/or evolving SBA programs and services to address long-term capital access gaps faced by small businesses and the investment managers that seek to support them. The Committee will only undertake tasks assigned to it by the Administrator. The **Federal Register** Notice will be published 15 days prior to filing the charter with Congress.

This notice is provided in accordance with the Federal Advisory Committee Act.

Dated: July 25, 2022.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2022–16243 Filed 7–28–22; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2022–0038]

Public Availability of Social Security Administration Fiscal Year (FY) 2020 Service Contract Inventory

AGENCY: Social Security Administration.

ACTION: Notice of public availability of FY 2020 service contract inventories.

SUMMARY: In accordance with the Consolidated Appropriations Act of 2010, we are publishing this notice to advise the public of the availability of

[17] 17 CFR 200.30–3(a)(12).

the FY 2020 Service Contract inventory. This inventory provides information on FY 2020 service contract actions over $25,000. We organized the information by function to show how we distribute contracted resources throughout the agency. We developed the inventory in accordance with guidance issued on December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *https://obamawhitehouse.archives.gov/sites/default/files/omb/procurement/memo/service-contract-inventory-guidance.pdf.* You can access the inventory and summary of the inventory on our homepage at the following link: *http://www.socialsecurity.gov/sci.*

FOR FURTHER INFORMATION CONTACT: Ronnetta Mason, Office of Budget, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401. Phone (410) 597–1955, email *Ronnetta.Mason@ssa.gov.*

Michelle King,

Deputy Commissioner for Budget, Finance, and Management.

[FR Doc. 2022–16280 Filed 7–28–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11796]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Murillo: From Heaven to Earth'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Murillo: From Heaven to Earth'' at the Kimbell Art Museum, Fort Worth, Texas, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–16268 Filed 7–28–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11798]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Scandinavian Design and the United States, 1890–1980'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Scandinavian Design and the United States, 1890–1980'' at the Los Angeles County Museum of Art, Los Angeles, California; the Milwaukee Art Museum, Milwaukee, Wisconsin; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–16267 Filed 7–28–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11800]

Department of State FY 2020 Service Contract Inventory

ACTION: Notice of release of the Department of State's FY 2020 service contract inventory.

SUMMARY: Acting in compliance with Section 743 of Division C of the Consolidated Appropriations Act of 2010, the Department of State is publishing this notice to advise the public of the availability of the FY 2020 Service Contract Inventory. The FY 2020 Service Contract Inventory includes the FY 2020 Planned Analysis, and the FY 2019 Meaningful Analysis. The inventory was developed in accordance with guidance issued by the Office of Management and Budget (OMB), Office of Federal Procurement Policy (OFPP). The Department of State has posted its FY 2020 Service Contract Inventory at the following link: *https://csm.state.gov/index2.html.*

DATES: The inventory is available on the Department's website as of July 9, 2022.

FOR FURTHER INFORMATION CONTACT: Marlon D. Henry, Management and Program Analyst, A/EX/CSM, 202–485–7210, *HenryMD@state.gov.*

Marlon D. Henry,

Management and Program Analyst, Collaborative Strategy and Management Division, Bureau of Administration, Department of State.

[FR Doc. 2022–16319 Filed 7–28–22; 8:45 am]

BILLING CODE 4710–24–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36631]

Livonia, Avon & Lakeville Railroad Corporation—Acquisition of Control Exemption—Ontario Midland Railroad Corporation

Livonia, Avon & Lakeville Railroad Corporation (LAL), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of the Ontario Midland

Railroad Corporation (OMID), a Class III rail carrier.

The verified notice states that LAL will acquire control of OMID by purchasing 55% of OMID stock pursuant to a Stock Acquisition Agreement. An agreement is expected to be executed on or about August 13, 2022. The verified notice states that LAL currently controls two Class III rail carriers, Western New York & Pennsylvania Railroad, LLC (WNYP) and B&H Rail Corporation (B&H) [1] (collectively, LAL Class III Affiliates).

LAL represents that: (1) the rail lines on which OMID will operate will not connect with the rail lines operated by LAL or the LAL Class III Affiliates; (2) the transaction is not part of a series of anticipated transactions that would result in a connection between lines operated or to be operated by OMID, LAL, or the LAL Class III Affiliates; and (3) the transaction does not involve a Class I rail carrier. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d) (2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

The transaction may be consummated on or after August 12, 2022, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 5, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36631, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on LAL's representative, Kevin M. Sheys, Hogan Lovells US LLP, 555 13th Street NW, Washington, DC 20004.

According to LAL, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: July 25, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2022–16304 Filed 7–28–22; 8:45 am]

BILLING CODE 4915–01–P

[1] The verified notice states that LAL, B&H, and OMID operate in New York, and WNYP operates in New York and Pennsylvania.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36626]

OmniTRAX Holdings Combined, Inc., and HGS Railway Holdings, Inc.—Continuance in Control Exemption—Omni River Ridge, LLC d/b/a River Ridge Railroad

AGENCY: Surface Transportation Board.

ACTION: Correction to notice of exemption.

OmniTRAX Holdings Combined, Inc. (OmniTRAX), and HGS Railway Holdings, Inc. (HGS) (collectively, Omni-HGS), both noncarriers, filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to continue in control of Omni River Ridge, LLC d/b/a River Ridge Railroad (RRR), a noncarrier controlled by OmniTRAX, upon RRR's becoming a Class III rail carrier.[1] On July 15, 2022, notice of the exemption was served and published in the **Federal Register** (87 FR 42,537). The exemption is scheduled to become effective on July 29, 2022.

The served notice inadvertently omitted the effective date of the exemption. The notice should have stated that the transaction may be consummated on or after July 29, 2022, the effective date of the exemption (30 days after the verified notice was filed). This notice corrects that error.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time.

All pleadings, referring to Docket No. FD 36626, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Omni-HGS's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 29, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Eden Besera,

Clearance Clerk.

[FR Doc. 2022–16313 Filed 7–28–22; 8:45 am]

BILLING CODE 4915–01–P

[1] This transaction is related to a verified notice of exemption filed concurrently in *Omni River Ridge, LLC d/b/a River Ridge Railroad—Operation Exemption—in Clark County, Ind.,* Docket No. FD 36625, in which Omni River Ridge, LLC, seeks to operate approximately 0.943 miles of track in Clark County, Ind.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36632]

Hood River Railroad LLC—Acquisition and Operation Exemption—Mt. Hood Railroad Company

Hood River Railroad LLC (HRR), a noncarrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.31 to acquire from Mt. Hood Railroad Company (MHR) and operate an approximately 21.14-mile rail line extending between milepost 0.0 at Hood River, Or., (at a point of connection with a line of the Union Pacific Railroad Company), and milepost 21.14 at Parkdale, Or. (the Line), which constitutes MHR's entire rail system.

According to the verified notice, HRR and MHR are corporate affiliates indirectly controlled by L. Scott Webster (Mr. Webster). HRR further states that, upon consummation of the transaction, MHR will cease to be a railroad common carrier, and HRR will become one in MHR's place under the indirect control of Mr. Webster. HRR also states that the proposed transaction would facilitate Mr. Webster's longer-term plans to dissolve MHR after resolving MHR's corporate and tax affairs.

According to HRR, the proposed transaction does not include an interchange commitment. HRR certifies that its projected annual revenue will not exceed $5 million and that the proposed transaction will not result in HRR's becoming a Class I or II rail carrier.

The earliest this transaction may be consummated is August 13, 2022, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d)

may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 5, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36632, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on HRR's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to HRR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: July 25, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2022–16314 Filed 7–28–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–1032]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Flight Operations Quality Assurance (FOQA) Program

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves the voluntary submission of information gained through the Flight Operations Quality Assurance (FOQA) Program. FOQA is a voluntary safety program designed to improve aviation safety through the proactive use of flight-recorded data. The information collected will allow operators to use this data to identify and correct deficiencies in all areas of flight operations. DATES: Written comments should be submitted by September 27, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Sandra L. Ray, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: John Lusk by email at: *john.lusk@faa.gov;* phone: 303–342–1211.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0660.

Title: Flight Operations Quality Assurance (FOQA) Program.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: Flight Operations Quality Assurance (FOQA) is a voluntary safety program designed to improved aviation safety through the proactive use of flight-recorded data. Operators will use this data to identify and correct deficiencies in all areas of flight operations. Properly used, FOQA data can reduce or eliminate safety risks, as well as minimize deviations from regulations. Through access to de-identified aggregate FOQA data, the Federal Aviation Administration (FAA) can identify and analyze national trends and target resources to reduce operational risks in the National Airspace System (NAS), air traffic control (ATC), flight operations and airport operations.

The FAA and the air transportation industry have sought additional means for addressing safety problems and identifying potential safety hazards. Based on the experiences of foreign air carriers, the results of several FAA-sponsored studies, and input received from government/industry safety forums, the FAA concluded that wide implementation of FOQA programs could have significant potential to reduce air carrier accident rates below current levels. The value of FOQA programs is the early identification of adverse safety trends, which, if uncorrected, could lead to accidents. A key element in FOQA is the application of corrective action and follow-up to ensure that unsafe conditions are effectively remediated.

Respondents: 72 Air Carriers (57 with existing programs and 15 with new programs).

Frequency: Once for certificate holders requesting a new program, monthly for certificate holders with an existing program.

Estimated Average Burden per Response: 100 hours for new respondents, 30 hours for annually for existing respondents.

Estimated Total Annual Burden: 100 hours for new respondents, 30 hours annually for each existing respondent.

Issued in Washington, DC, on July 26, 2022.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2022–16340 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number MARAD–2019–0011]

Deepwater Port License Application: SPOT Terminal Services LLC—Final General Conformity Determination

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of Final General Conformity Determination.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the availability of the Final General Conformity Determination to ensure that the air emissions associated with the proposed Sea Port Oil Terminal (SPOT) Deepwater Port Project (Project or SPOT Project) conform with the Texas State Implementation Plan (SIP). The SPOT Project proposes to provide United States (U.S.) crude oil loading services on very large crude carriers (VLCCs) and other crude oil carriers for export to the global market. A detailed description of the proposed project and prior federal action is provided under the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: The SPOT Deepwater Port License Application, the FEIS, this Final General Conformity Determination, and other associated documents are available for viewing at *https://*

www.regulations.gov under docket number MARAD–2019–0011 (*https://www.regulations.gov/docket/MARAD-2019-0011*).

The public docket for the SPOT Deepwater Port License Application is maintained by the U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826; the fax number is 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. Efrain Lopez, MARAD, via telephone at (202) 366–9761 or email at *SPOT_EIS@dot.gov*; and Mr. Matthew Layman, USCG, via telephone at (202) 372–1421 or email at *DeepwaterPorts@uscg.mil.* Include MARAD–2019–0011 in the subject line of the message and provide your comments in the body of the email or as an attachment.

SUPPLEMENTARY INFORMATION:

Prior Federal Action

A Notice of Application that summarized the SPOT Deepwater Port License Application was published in the **Federal Register** on March 4, 2019 (84 FR 7413). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Scoping Meeting was published in the **Federal Register** on March 7, 2019 (84 FR 8401). A Notice of Availability of the Draft Environmental Impact Statement (DEIS) and Notice of Public Meeting was published in the **Federal Register** on February 7, 2020 (85 FR 7381). A Notice of Availability of the Draft General Conformity Determination was published in the **Federal Register** on October 8, 2021 (86 FR 56349). A Notice of Availability of the Supplemental Draft Environmental Impact Statement (SDEIS) and Notice of Public Meetings was published in the **Federal Register** on October 29, 2021 (86 FR 60093). A Notice of Availability of the Final Environmental Impact Statement (FEIS) is being published simultaneously with this announcement under a separate notice. It is noted that comments received on the Draft General Conformity are addressed in the following appendices of the SPOT FEIS: Appendix C2—Comments on the Supplemental Draft EIS and Appendix V—Final General Conformity Determination.

Background

On January 31, 2019, MARAD and USCG received an application from SPOT for all Deepwater Ports related Federal authorizations required for a license to own, construct, and operate a deepwater port for the export of oil. The proposed deepwater port would be located in Federal waters approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas. Texas was designated as the Adjacent Coastal State for the SPOT license application.

The Federal agencies opened a 30-day public comment period for the Draft General Conformity Determination that began on October 8, 2021, and ended on November 7, 2021. The purpose of this Final General Conformity Determination is to ensure that the air emissions associated with the SPOT Project conform with the Texas SIP in accordance with 40 CFR part 93, subpart B. The Final General Conformity Determination is available for public review at the Federal docket website: *https://www.regulations.gov* under docket number MARAD–2019–0011. As aforementioned, a Notice of Availability of the FEIS is being published simultaneously with this announcement.

This review and determination is triggered by air emissions from construction activities proposed by SPOT Terminal, LLC (the Applicant) that would exceed the applicable General Conformity *de minimis* threshold of 50 tons per year of nitrogen oxides or volatile organic compounds set by *Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas Classified as Moderate for the 2008 Ozone National Ambient Air Quality Standards,* published in the **Federal Register** on August 23, 2019 (84 FR 44238), within the Houston-Galveston-Brazoria (HGB) area. The HGB area includes Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller counties and extends nine nautical miles offshore over state water.

Summary of the License Application

The proposed SPOT Deepwater Port (DWP) would be located in the U.S. Exclusive Economic Zone in the Gulf of Mexico, in Galveston Area Outer Continental Shelf lease blocks 463 and A–59, approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas, in water depths of approximately 115 feet. The proposed project's onshore components would be located in both Brazoria and Harris counties.

The overall project would consist of both onshore and offshore marine components. The onshore components would consist of:

- Modifications to the existing Enterprise Crude Houston (ECHO) Terminal, including four electric motor-driven mainline crude oil pumps, four electric motor-driven booster crude oil pumps, and one measurement skid to support the delivery of crude oil to the proposed Oyster Creek Terminal;
- One 50.1-mile, 36-inch-diameter ECHO to Oyster Creek Pipeline;
- One pipeline interconnection from the existing Rancho II 36-inch-diameter pipeline to the ECHO to Oyster Creek Pipeline (Rancho II Junction);
- A new Oyster Creek Terminal on approximately 140 acres of land, including six electric motor-driven mainline crude oil pumps with the capacity to push crude oil to the offshore pipelines at a rate of up to 85,000 bph, four electric motor-driven booster crude oil pumps, seven aboveground storage tanks (each with a capacity of 685,000 barrels [600,000 barrels of working storage]) for a total onshore storage capacity of approximately 4.8 million barrels (4.2 million barrels working storage) of crude oil, metering equipment, two permanent and one portable vapor combustion units, and a firewater system;
- Two collocated 12.2-mile, 36-inch-diameter Oyster Creek to Shore Pipelines; and
- Ancillary facilities for the onshore pipelines, including ten mainline valves, of which six would be along the ECHO to Oyster Creek Pipeline and four along the Oyster Creek to Shore Pipelines, pig launchers for the ECHO to Oyster Creek Pipeline, and pig launchers and receivers for the Oyster Creek to Shore Pipelines.

The offshore and marine components would consist of:

- Two collocated, bi-directional, 46.9-mile, 36-inch-diameter crude oil offshore pipelines for crude oil delivery from the Oyster Creek Terminal to the platform; and
- Nine nautical miles of the above-mentioned forms part of the Final General Conformity Determination.

As stated, the purpose of this notice is to announce the availability of the Final General Conformity Determination to ensure that the SPOT Project conforms with the Texas SIP.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please

visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–15966 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number MARAD–2019–0011]

Deepwater Port License Application: SPOT Terminal Services LLC—Final Environmental Impact Review

AGENCY: Maritime Administration, Department of Transportation

ACTION: Notice of availability; notice of final hearing; request for comments.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the availability of the Final Environmental Impact Statement (FEIS) for the SPOT Terminal Services LLC (SPOT) deepwater port license application for the export of crude oil from the United States to nations abroad. The SPOT deepwater port license application describes a proposed project that would be located approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas. Publication of this notice begins a 45-day comment period, requests public participation in the final environmental impact review process, provides information on how to participate in the final environmental impact review process, and announces the availability of an informational website and a virtual Final Hearing that will be held via Zoom. Registration information is provided in the *Virtual Final Hearing and Informational website* section of this notice. A Notice of Availability of the Final General Conformity Determination is being published simultaneously with this announcement under a separate notice.

DATES: Comments on the FEIS must be received on or before 45 days from the date of publication of this **Federal Register** Notice. MARAD and USCG will hold one virtual public Final Hearing in connection with the SPOT FEIS. This Final Hearing will be held via Zoom on August 23, 2022, from 6:00 p.m. to 8:00 p.m. Central Daylight Time (CDT). The Final Hearing will end no earlier than 8:00 p.m. CDT, but it may end later than the stated time, depending on the number of persons who wish to comment on the record. Anyone interested in attending the virtual public meeting or speaking during the virtual public meeting must register. Additionally, materials submitted in response to this request for comments on the FEIS must be submitted to the *www.regulations.gov* website or the Federal Docket Management Facility as detailed in the **ADDRESSES** section below by the end of the comment period.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0011 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* search MARAD–2019–0011 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* The Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2019–0011, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590. Due to flexible work schedules in response to Covid 19, call 202–493–0402 to determine facility hours prior to hand delivery.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, and/or a telephone number on a cover page so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: MARAD via email at *SPOT_EIS@dot.gov*; and the USCG via email at *DeepwaterPorts@uscg.mil.* Include MARAD–2019–0011 in the subject line of the message. For written comments and other material submissions, please follow the directions under **ADDRESSES** above, and do not submit written comments or other materials to the email addresses in this section. Improperly submitted comments interfere with MARAD's ability to help others seeking assistance with comment submission or public meeting attendance. Improperly submitted comments may be rejected from consideration.

SUPPLEMENTARY INFORMATION:

Prior Federal Action

A Notice of Application that summarized the SPOT Deepwater Port License Application was published in the **Federal Register** on March 4, 2019 (84 FR 7413). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Scoping Meeting was published in the **Federal Register** on March 7, 2019 (84 FR 8401). A Notice of Availability of the Draft Environmental Impact Statement (DEIS) and Notice of Public Meeting was published in the **Federal Register** on February 7, 2020 (85 FR 7381). A Notice of Availability of the Draft General Conformity Determination was published in the **Federal Register** on October 8, 2021 (86 FR 56349). A Notice of Availability of the Supplemental Draft Environmental Impact Statement (SDEIS) and Notice of Public Meeting was published in the **Federal Register** on October 29, 2021 (86 FR 60093).

Request for Comments

We request public comments or other relevant information related to the FEIS for the proposed SPOT deepwater port. These comments will inform MARAD's Record of Decision. We encourage you to review the information on the website and attend the virtual Final Hearing. Also, you may submit comments electronically. It is preferred that comments be submitted electronically. Please see the information in the **ADDRESSES** section above on how to properly submit comments. All comments submitted to the docket via *www.regulations.gov* or delivered to the Federal Docket Management Facility will be posted, without change, to the Federal Docket Management Facility website (*http://www.regulations.gov*) and will include any personal information you provide. Therefore, submitting such information makes it public. You may view docket submissions at the DOT Docket Management Facility or electronically at the *www.regulations.gov* website.

Virtual Final Hearing and Informational Website

You are invited to learn about the proposed SPOT deepwater port via the informational website (*www.SPOTNEPAProcess.com*). You are also invited to attend the virtual Final Hearing and encouraged to provide comments on the proposed action and the environmental impact analysis contained in the FEIS for the proposed SPOT deepwater port. Speakers must register for the virtual Final Hearing via the informational website. Speakers may also register via phone number (888)

731–5089. To register for the final hearing on August 23, please leave your name along with the correct spelling and phone number after the tone. When registering, please indicate if you would like the opportunity to provide a live comment during the meeting or if you are participating to listen only. Speakers will be recognized in the following order during the Final Hearing: elected officials, public agency representatives, and then individuals or groups in the order in which they registered. In order to accommodate all speakers, speaker time may be limited, meeting hours may be extended, or both. Speakers' transcribed remarks will be included in the public docket. You may also submit written material for inclusion in the public docket. Written material must include the author's name. We ask attendees to respect the meeting procedures in order to ensure a constructive information-gathering session. The presiding officer will use his/her discretion to conduct the meeting in an orderly manner.

The Final Hearing will be conducted in English; however, translation services will be provided in Spanish and Vietnamese. Final Hearing attendees who require special assistance, such as translation services or other reasonable accommodation, please notify MARAD and USCG (see **FOR FURTHER INFORMATION CONTACT**) at least five business days in advance. Please include contact information as well as information about specific needs.

Background

On January 31, 2019, MARAD and USCG received a license application from SPOT for a license to own, construct, and operate a deepwater port for the export of crude oil. The proposed deepwater port would be located in the U.S. Exclusive Economic Zone, approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas. Texas was designated as the Adjacent Coastal State (ACS) for the SPOT license application.

The Federal agencies involved held a public scoping meeting in connection with the evaluation of the SPOT license application. The public scoping meeting was held in Lake Jackson, Texas, on March 20, 2019. The transcript of the scoping meeting is included on the public docket at *https://www.regulations.gov/document/MARAD-2019-0011-0019.* The Federal agencies also held a Draft EIS public comment meeting to receive comments on the Draft EIS. The public comment meeting was held in Lake Jackson, Texas on February 26, 2020. A second 30-day public comment period due to COVID began on May 1, 2020 and ended on May 31, 2020. The transcripts of the DEIS public comment meetings are also included on the public docket at *https://www.regulations.gov/document/MARAD-2019-0011-1192.*

The Federal agencies also held a Supplemental DEIS public comment meeting to receive comments on the SDEIS. The public meeting was held virtually on November 16, 2021. The transcripts of the SDEIS public comment meetings are also included on the public docket at *https://www.regulations.gov/docket/MARAD-2019-0011.* The Federal agencies also opened a 30-day public comment period for the Draft General Conformity Determination that began on October 8, 2021, and ended on November 7, 2021.

The purpose of the FEIS is to analyze the direct, indirect, and cumulative environmental impacts of the proposed action, and to identify and analyze the environmental impacts of a reasonable range of alternatives. The FEIS is currently available for public review and comment at the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0011. As stated previously, a Notice of Availability of the Final General Conformity Determination is being simultaneously published with this announcement.

Summary of the License Application

SPOT is proposing to own, construct, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 85,000 barrels per hour (bph). The SPOT deepwater port would allow for up to two Very Large Crude Carriers (VLCCs) or other crude oil carriers to moor at single point mooring (SPM) buoys and connect with the deepwater port via floating connecting crude oil hoses and a floating vapor recovery hose. The maximum frequency of loading VLCCs or other crude oil carriers would be 2 million barrels per day, 365 days per year.

The overall project would consist of offshore and marine components as well as onshore components, as described below.

The SPOT deepwater port offshore and marine components would consist of the following:

- One fixed offshore platform with eight piles in Galveston Area Outer Continental Shelf lease block 463, approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas, in a water depth of approximately 115 feet. The fixed offshore platform would be comprised of four decks, including: a sump deck with shut-down valves and open-drain sump; a cellar deck with pig launchers and receivers, generators, and three vapor combustion units; a main deck with a lease automatic custody transfer (LACT) unit, oil displacement prover loop, living quarters, electrical and instrument building, and other ancillary equipment; and a laydown deck with a crane laydown area.
- Two single point mooring buoys (SPMs), each having: two (2) 24-inch inside diameter crude oil underbuoy hoses interconnecting with the crude oil pipeline end manifold (PLEM); two 24-inch inside diameter floating crude oil hoses connecting the moored VLCC or other crude oil carrier for loading to the SPM buoy; one 24-inch inside diameter vapor recovery underbuoy hose interconnecting with the vapor recovery PLEM; and one 24-inch inside diameter floating vapor recovery hose to connect to the moored VLCC or other crude oil carrier for loading. The floating hoses would be approximately 800 feet in length and rated for 300 psig (21-bar). Each floating hose would contain an additional 200 feet of 16-inch ''tail hose'' that is designed to be lifted and robust enough for hanging over the edge railing of the VLCC or other crude oil vessels. The underbuoy hoses would be approximately 160 feet in length and rated for 300 psig (21-bar).
- Four PLEMs would provide the interconnection between the pipelines and the SPM buoys. Each SPM buoy would have two (2) PLEMs—one PLEM for crude oil and one PLEM for vapor recovery. Each crude oil loading PLEM would be supplied with crude oil by two 30-inch outside diameter pipelines, each approximately 0.66 nautical miles in length. Each vapor recovery PLEM would route recovered vapor from the VLCC or other crude oil carrier through the PLEM to the three vapor combustion units located on the platform topside via two 16-inch outside diameter vapor recovery pipelines, each approximately 0.66 nautical miles in length.
- Two co-located 36-inch outside diameter, 40.8-nautical mile-long crude oil pipelines would be constructed from the shoreline crossing in Brazoria County, Texas, to the SPOT deepwater port for crude oil delivery. These pipelines, in conjunction with 12.2 statute miles of new-build onshore pipelines (described below), would connect the onshore crude oil storage facility and pumping station (Oyster Creek Terminal) to the offshore SPOT deepwater port. The crude oil would be metered at the offshore platform.

Pipelines would be bi-directional for the purposes of maintenance, pigging, changing crude oil grades, or evacuating the pipeline with water.

The SPOT deepwater port onshore storage and supply components would consist of the following:

- New equipment and piping at the existing Enterprise Crude Houston (ECHO) Terminal to provide interconnectivity with the crude oil supply network for the SPOT Project. This would include the installation of four booster pumps, one measurement skid, and four crude oil pumps.
- An interconnection between the existing Rancho II pipeline and the proposed ECHO to Oyster Creek pipeline consisting of a physical connection as well as ultrasonic measurement capability for pipeline volumetric balancing purposes.
- The proposed Oyster Creek Terminal located in Brazoria County, Texas, on approximately 140 acres of land consisting of seven aboveground storage tanks, each with a total storage capacity of 685,000 barrels (600,000 barrels working storage capacity), for a total onshore storage capacity of approximately 4.8 million barrels (4.2 million barrels working storage) of crude oil. The Oyster Creek Terminal also would include: Six (6) electric-driven mainline crude oil pumps; four electric-driven booster crude oil pumps (two per pipeline), working in parallel to move crude oil from the storage tanks through the measurement skids; two crude oil pipeline pig launchers/receivers; one crude oil pipeline pig receiver; two measurement skids for measuring incoming crude oil—one skid located at the incoming pipeline from the existing ECHO Terminal, and one skid installed and reserved for a future pipeline connection; two measurement skids for measuring departing crude oil; three vapor combustion units—two permanent and one portable; and ancillary facilities to include electrical substation, office, and warehouse buildings.
- Three onshore crude oil pipelines would be constructed onshore to support the SPOT deepwater port. These would include: one 50.1 statute mile long 36-inch crude oil pipeline from the existing ECHO Terminal to the Oyster Creek Terminal. This pipeline would be located in Harris County and Brazoria County, Texas; two 12.2 statute mile long, co-located 36-inch crude oil export pipelines from the Oyster Creek Terminal to the shore crossing where these would join the above-described subsea pipelines supplying the SPOT deepwater port. These pipelines would be located in Brazoria County, Texas.

As previously stated, the purpose of this notice is to announce that the FEIS is currently available for public review and a 45-day public comment period. Comments can be submitted through the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0011.

Public Participation Instructions

How long do I have to submit comments?

We are providing a 45-day comment period.

How do I prepare and submit comments?

To ensure that your comments are correctly filed in the Docket, please include the docket number shown at the beginning of this document in your comments.

If you are submitting comments electronically as a PDF (Adobe) File, MARAD and USCG ask that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing the agencies to search and copy certain portions of your submissions. Comments may be submitted to the docket electronically at *http://www.regulations.gov.* Search using the MARAD docket number in this notice and follow the online instructions for submitting comments.

You may also submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *https://www.whitehouse.gov/omb/information-regulatory-affairs/information-policy/*. DOT's guidelines may be accessed at *https://www.bts.gov/statistical-policy* and also at *https://www.transportation.gov/dot-information-dissemination-quality-guidelines.*

I provided MARAD and USCG comments on the SPOT FEIS, orally or in writing, in another forum. May I provide comments in response to this notice as well?

Yes, MARAD and USCG encourage any member of the public to submit relevant comments for the docket, including input that has previously been communicated to the agencies.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

Will the agency consider late comments?

MARAD and USCG will consider all substantive comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket Management Unit are indicated above in the same location. You may also see the comments on the internet. To read the comments on the internet, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. Please note that even after the comment closing date, MARAD will continue to file relevant information in the Docket as it becomes available. Accordingly, we recommend that you periodically check the Docket for new material.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93)

By order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–15965 Filed 7–28–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Office of Foreign Assets Control Information Collection Requests

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 29, 2022 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Office of Foreign Assets Control (OFAC)

1. Title: OFAC Application for the Release of Blocked Funds.

OMB Number: 1505–0170.

Description: Transactions prohibited pursuant to the Trading With the Enemy Act, *50 U.S.C. 4301–4341,* the International Emergency Economic Powers Act, *50 U.S.C. 1701 et seq.,* and other authorities may be authorized by means of specific licenses issued by OFAC. Such licenses are issued in response to applications submitted by persons whose property and interests in property have been blocked or who wish to engage in transactions that would otherwise be prohibited. The OFAC Application for the Release of Blocked Funds, which provides a standardized method of application for all applicants seeking the unblocking of funds, is available in electronic format on OFAC's website. By obviating the need for applicants to write lengthy letters to OFAC, this form and the electronic portal reduce the overall burden of the application process. Applications to OFAC for the release of blocked funds are strongly encouraged to be made via the electronic licensing portal here: *https://home.treasury.gov/policy-issues/financial-sanctions/ofac-license-application-page.*

Type of Review: Extension without change of a currently approved collection.

Affected Public: Businesses or other for-profits, individuals and households, and non-governmental organizations.

Estimated Number of Respondents: 6,700.

Frequency of Response: 1 per respondent.

Estimated Total Number of Annual Responses: 6,700.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 3,350 hours.

2. *Title:* Persons Providing Travel and Carrier Services to Cuba.

OMB Number: 1505–0168.

Type of Review: Extension without change of a currently approved collection.

Form Number: Section 515.572 does not specify any particular form of recordkeeping.

Description: Requirements to retain records are codified in § 515.572 of the Cuban Assets Control Regulations, *31 CFR part 515* (the ''Regulations''). Persons subject to U.S. jurisdiction who provide authorized travel or carrier services related to Cuba are required to maintain for at least five years from the date of the transaction a certification from each customer indicating the name and address of each customer and the section of the Regulations (in the case of generally licensed travel), or the specific license number, that authorizes the person to travel to Cuba.

The records covered by this information collection must be provided on request to the U.S. Department of the Treasury, and support OFAC's implementation of its compliance and enforcement programs pursuant to the Regulations.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Businesses or other for-profits, individuals and households, and non-governmental organizations.

Estimated Number of Respondents: 565,000 respondents per year.

Estimated Number of Records per Respondent: 1 per respondent.

Estimated Total Number of Annual Records: 565,000 records.

Estimated Time per Record: 1 minute per record.

Estimated Total Annual Burden Hours: 9,417 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2022–16246 Filed 7–28–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0515]

Agency Information Collection Activity: Maintenance of Records Under 38 CFR 36.4333

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 29, 2022. (Inserted by the Clearance Officer.)

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0515'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0515'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR 36.4317.

Title: Maintenance of Records Under 38 CFR 36.4333.

OMB Control Number: 2900–0515.

Type of Review: Revision.

Abstract: VA is submitting this revised information collection in advance of implementing new technology and oversight procedures in which VA will collect from lenders certain loan origination information via a computable electronic format. The information collected under § 36.4333 is used by VA to ensure lenders and servicers who participate in VA's Loan Guaranty program follow statutory and regulatory requirements, such as those

relating to credit information, loan processing requirements, underwriting standards, servicing requirements, and other applicable laws, regulations and policies. VA also uses data collected under this authority to provide annual feedback to lenders, through the Lender Scorecard, on certain loan characteristics such as interest rate, fees and charges, audit results, etc., as compared to the national average of all VA lenders.

The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 11369 on May 26, 2022, page 32076.

Affected Public: Private Sectors.

Estimated Annual Burden: 14,983 hours.

Estimated Average Burden per Respondent: 0.01 hours.

Frequency of Response: 2.9 times.

Estimated Number of Respondents: 1,385,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–16282 Filed 7–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0422]

Agency Information Collection Activity: VA Acquisition Regulation (VAAR) Construction Provisions and Clauses

AGENCY: Office of Acquisition and Logistics, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Office of Acquisition and Logistics (OAL), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 27, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Bogdan Vaga, Office of Acquisition & Logistics, Procurement Policy & Warrant Management Services (003A2A), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Bogdan.Vaga@va.gov.* Please refer to ''OMB Control No. 2900–0422'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0422'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA. With respect to the following collection of information, OAL invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of OAL's functions, including whether the information will have practical utility; (2) the accuracy of OAL's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VA Acquisition Regulation (VAAR) Construction Provisions and Clauses.

OMB Control Number: 2900–0422.

Type of Review: Extension of a currently approved collection.

Abstract: This Paperwork Reduction Act (PRA) submission seeks renewal without changes of Office of Management and Budget (OMB) approval No. 2900–0422 for five collections of information for the Department of Veterans Affairs Acquisition Regulation (VAAR) clauses, as follows:

- Clause 852.232–70, Payment Under Fixed-Price Construction Contracts (without NAS–CPM), requires construction contractors, without NAS–CPM, to submit a schedule of costs for work to be performed under the contract.
- Clause 852.232–71, Payment Under Fixed-Price Construction Contracts (including NAS–CPM), requires construction contractors, including NAS–CPM, to submit a schedule of costs for work to be performed under the contract.
- Clause 852.236–72, Performance of Work by the Contractor, requires contractors awarded a construction contract containing Federal Acquisition Regulation (FAR) clause 52.236–1, Performance of Work by the Contractor, to submit a statement designating the branch or branches of contract work to be performed by the contractor's own forces.
- Clause 852.236–80, Subcontracts and Work Coordination, requires construction contractors, on contracts involving complex mechanical-electrical work, to furnish coordination drawings showing the manner in which utility lines will fit into available space and relate to each other and to the existing building elements.
- Clause 852.243–70, Construction Contract Changes-Supplement, requires contractors to submit cost proposals for changes ordered by the contracting officer or for changes proposed by the contractor.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 2,974 hours.

Estimated Average Burden per Respondent: 105 minutes.

Frequency of Response: More than quarterly.

Estimated Number of Respondents: 1,706.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–16289 Filed 7–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Request for Information on the Department of Veterans Affairs Ophthalmology Technician Standard of Practice

AGENCY: Department of Veterans Affairs.

ACTION: Request for information.

SUMMARY: The Department of Veterans Affairs (VA) is requesting information to assist in developing a national standard of practice for VA Ophthalmology

Technicians. VA seeks comments on various topics to help inform VA's development of this national standard of practice.

DATES: Comments must be received on or before September 27, 2022.

ADDRESSES: Comments may be submitted through *www.regulations.gov*. Comments received will be available at *www.regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Ethan Kalett, Office of Regulations, Appeals and Policy (10BRAP), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, or by phone at 202–461–0500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Authority

Chapters 73 and 74 of 38 U.S.C. and 38 U.S.C. 303 authorize the Secretary to regulate the professional activities of VA health care professions to make certain that VA's health care system provides safe and effective health care by qualified health care professionals to ensure the well-being of those Veterans who have borne the battle.

On November 12, 2020, VA published an interim final rule confirming that VA health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other requirements that unduly interfere with their practice. 38 CFR 17.419; 85 FR 71838. Specifically, this rulemaking confirmed VA's current practice of allowing VA health care professionals to deliver health care services in a State other than the health care professional's State of licensure, registration, certification, or other State requirement, thereby enhancing beneficiaries' access to critical VA health care services. The rulemaking also confirmed VA's authority to establish national standards of practice for health care professionals which would standardize a health care professional's practice in all VA medical facilities.

The rulemaking explained that a national standard of practice describes the tasks and duties that a VA health care professional practicing in the health care profession may perform and may be permitted to undertake. Having a national standard of practice means that individuals from the same VA health care profession may provide the same type of tasks and duties regardless of the VA medical facility where they are located or the State license, registration, certification, or other State requirement they hold. We emphasized in the rulemaking and reiterate that VA will determine, on an individual basis, that a health care professional has the necessary education, training and skills to perform the tasks and duties detailed in the national standard of practice and will only be able to perform such tasks and duties after they have been incorporated into the individual's privileges, scope of practice, or functional statement. The rulemaking explicitly did not create any such national standards and directed that all national standards of practice would be subsequently created via policy.

Need for National Standards of Practice

As the Nation's largest integrated health care system, it is critical that VA develops national standards of practice to ensure beneficiaries receive the same high-quality care regardless of where they enter the system and to ensure that VA health care professionals can efficiently meet the needs of beneficiaries when practicing within the scope of their VA employment. National standards are designed to increase beneficiaries' access to safe and effective health care, thereby improving health outcomes. The importance of this initiative has been underscored by the COVID–19 pandemic. With an increased need for mobility in our workforce, including through VA's Disaster Emergency Medical Personnel System, creating a uniform standard of practice better supports VA health care professionals who already frequently practice across State lines. In addition, the development of national standards of practice aligns with VA's long-term deployment of a new electronic health record (EHR). National standards of practice are critical for optimal EHR implementation to enable the specific roles for each health care profession in EHR to be consistent across the Veterans Health Administration (VHA) and to support increased interoperability between VA and the Department of Defense (DoD). DoD has historically standardized practice for certain health care professionals, and VHA closely partnered with DoD to learn from their experience.

Process To Develop National Standards of Practice

Consistent with 38 CFR 17.419, VA is developing national standards of practice via policy. There will be one overarching national standard of practice directive that will generally describe VHA's policy and have each individual national standard of practice as an appendix to the directive. The directive and all appendices will be accessible on VHA Publications website at: *https://vaww.va.gov/vhapublications/* (internal) and *https://www.va.gov/vhapublications/* (external) once published.

To develop these national standards, VA is using a robust, interactive process that is consistent with the guidance outlined in Executive Order (E.O.) 13132 to preempt State law. The process includes consultation with internal and external stakeholders, including State licensing boards, VA employees, professional associations, Veterans Service Organizations, labor partners and others. For each identified VA occupation, a workgroup comprised of health care professionals conducts State variance research to identify internal best practices that may not be authorized under every State license, certification, or registration, but would enhance the practice and efficiency of the profession throughout the agency. The workgroup may consult with internal stakeholders at any point throughout the process. If a best practice is identified that is not currently authorized by every State, the workgroup determines what education, training and skills are required to perform such task or duty. The workgroup then drafts a proposed VA national standard of practice using the data gathered during the State variance research and incorporates internal stakeholder feedback to date.

The proposed national standard of practice is internally reviewed, to include by an interdisciplinary workgroup consisting of representatives from Quality Management; Field Chief of Staff; Academic Affiliates; Associate Director Patient Care Services; Ethics; Workforce Management and Consulting; Surgery; Credentialing and Privileging; Field Chief Medical Office; and EHR Modernization.

Externally, the proposed national standard of practice is provided to our partners in DoD. In addition, VA labor partners are engaged informally as part of a pre-decisional collaboration. Consistent with E.O. 13132, a letter is sent to each State board and certifying organization that includes the proposed national standard and an opportunity to further discuss the national standard with VA. After the States have received notification, the proposed national standard of practice is published to the **Federal Register** for 60 days to obtain feedback from the public, including professional associations and unions. At the same time, the proposed national standard is published on an internal VA site to obtain feedback from VA employees. Feedback from State boards,

professional associations, unions, VA employees and any other person or organization who informally provides comments via the **Federal Register** will be reviewed. VA will make appropriate revisions in light of the comments, including those that present evidence-based practice and alternatives that help VA meet our mission and goals, and that are better for Veterans or VA health care professionals. We will publish a collective response to all comments at *https://www.va.gov/standardsof practice.*

After the national standard of practice is finalized, approved and published in VHA policy, VA will implement the tasks and duties authorized by that national standard of practice. Any tasks or duties included in the national standard will be incorporated into an individual health care professional's privileges, scope of practice, or functional statement following any training and education necessary for the health care professional to perform those functions. Implementation of the national standard of practice may be phased in across all medical facilities, with limited exemptions for health care professionals as needed.

National Standard for Ophthalmology Technicians

The proposed format for national standards of practice when there is a national certifying body is as follows. The first paragraph is general information about the profession and what the health care professionals can do. The second paragraph references the education, certification, license, registration, or other requirements needed to practice this profession at VA and confirms that this profession follows the standard of practice set by the certifying body. A final statement confirms that as of the date of the workgroup's research into requirements, all individuals in this profession follow the same standard of practice.

We note that proposed standards of practice do not contain an exhaustive list of every task this profession can perform. Rather, it is designed to highlight whether there are any areas of variance in how this profession can practice across States and how this profession will be able to practice within VA notwithstanding their State license, certification, registration, and other requirements.

VA qualification standards require Ophthalmology Technicians to have an active, current, full and unrestricted national certification from the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO). VA reviewed whether there are any alternative registrations, certifications, or State requirements that could be required for an Ophthalmology Technician and found that there were none. VA proposes to adopt a standard of practice consistent with the national certification; therefore, VA Ophthalmology Technicians will continue to follow the same standard as set by their national certification. The standard of practice for the national registration can be found here: *https://documents.jcahpo.org/documents/Certification/IJCAHPO_Core_Criteria.pdf.*

Because the practice of Ophthalmology Technicians is not changing, there will be no impact on the practice of this occupation when this national standard of practice is implemented.

Proposed National Standard of Practice for Ophthalmology Technicians

Ophthalmology Technicians are eye health care professionals qualified to assist ophthalmologists in the diagnostic evaluation, management, treatment and education of patients with medical and surgical conditions affecting the visual system. Their duties include, but are not limited to, documenting patient histories, assessing visual and ocular function, performing tests and ophthalmology imaging, administering topical ocular medications (*i.e.,* drops or ointment, including anesthetic, dye, dilation, cycloplegic or antibiotics) and providing patient care.

Ophthalmology Technicians in VA possess the required education and certification from JCAHPO, in accordance with VA qualification standards, as more specifically described in VA Handbook 5005, Staffing, Part II, Appendix G52.

This national standard of practice confirms Ophthalmology Technicians practice in accordance with the Allied Ophthalmology Personnel Certification standards from JCAHPO, which are available at: *https://jcahpo.org/.* As ofAugust 2021, Ophthalmology Technicians in all States follow this national certification.

Request for Information

1. Are there any required trainings for the aforementioned practices that we should consider?

2. Are there any factors that would inhibit or delay the implementation of the aforementioned practices for VA health care professionals in any States?

3. Is there any variance in practice that we have not listed?

4. What should we consider when preempting conflicting State laws, regulations or requirements regarding supervision of individuals working toward obtaining their license or unlicensed personnel?

5. Is there anything else you would like to share with us about this national standard of practice?

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on July 18, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Policy Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2022–16325 Filed 7–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0863]

Agency Information Collection Activity: VA Acquisition Regulation (VAAR) Clause 852.237–73, Crime Control Act—Requirement for Background Checks

AGENCY: Office of Acquisition and Logistics, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Office of Acquisition and Logistics (OAL), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 27, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Bogdan Vaga, Office of Acquisition & Logistics, Procurement Policy & Warrant Management Services (003A2A), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC

20420 or email to *Bogdan.Vaga@va.gov.* Please refer to ''OMB Control No. 2900–0863'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0863'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA. With respect to the following collection of information, OAL invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of OAL's functions, including whether the information will have practical utility; (2) the accuracy of OAL's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VA Acquisition Regulation (VAAR) Construction Provisions and Clauses.

OMB Control Number: 2900–0863.

Type of Review: Extension of a currently approved collection.

Abstract: This Paperwork Reduction Act (PRA) submission seeks renewal without changes of Office of Management and Budget (OMB) approved No.2900–0863, VAAR clause 852.237–73, Crime Control Act—Requirement for Background Checks. Under the Crime Control Act of 1990 (34 U.S.C. 20351), each agency of the Federal Government, and every facility operated by the Federal Government, or operated under contract with the Federal Government, that hires, or contracts for hire, individuals involved with the provision to children under the age of 18 of childcare services shall assure that all existing and newly hired employees undergo a criminal history background check. VAAR clause 852.237–73, Crime Control Act—Requirement for Background Checks, is required in all solicitations, contracts, and orders that involve providing childcare services to children under the age of 18, including social services, health and mental health care, child-(day) care, education (whether or not directly involved in teaching), and rehabilitative programs covered under the statute.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 1,500 hours.

Estimated Average Burden per Respondent: 60 minutes.

Frequency of Response: One per contract employee.

Estimated Number of Respondents: 1,500.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–16286 Filed 7–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0586]

Agency Information Collection Activity: VA Acquisition Regulation (VAAR) Clause 852.211–72, Technical Industry Standards

AGENCY: Office of Acquisition and Logistics, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Office of Acquisition and Logistics (OAL), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 27, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Bogdan Vaga, Office of Acquisition & Logistics, Procurement Policy & Warrant Management Services (003A2A), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Bogdan.Vaga@va.gov.* Please refer to ''OMB Control No. 2900–0586'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0586'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA. With respect to the following collection of information, OAL invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of OAL's functions, including whether the information will have practical utility; (2) the accuracy of OAL's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VA Acquisition Regulation (VAAR) Construction Provisions and Clauses.

OMB Control Number: 2900–0586.

Type of Review: Extension of a currently approved collection.

Abstract: This Paperwork Reduction Act (PRA) submission seeks an extension of Office of Management and Budget (OMB) approval No. 2900–0586 for collection of information for both commercial and non-commercial item, service, and construction solicitations and contracts using VAAR Clause 852.211–72, Technical Industry Standards, as prescribed in CFR Title 48, Federal Acquisition Regulations System, VAAR 811.204–70, Contract clause. VAAR clause 852.211–72, Technical Industry Standards, requires that items offered for sale to VA under the solicitation conform to certain technical industry standards, such as United States Department of Agriculture (USDA) or the USDA Institutional Meat Purchase Specifications (IMPS) and that the contractor furnish evidence to VA

that the items meet that requirement. The evidence is normally in the form of a tag or seal affixed to the item, such as a label on beef product. In most cases, this requires no additional effort on the part of the contractor, as the items come from the factory with the tags already in place, as part of the manufacturer's standard manufacturing operation. Occasionally, for items not already meeting standards or for items not previously tested, a contractor will have to furnish a certificate from an acceptable laboratory certifying that the items furnished have been tested in accordance with, and conform to, the specified standards. Only firms whose products have not previously been tested to ensure the products meet the industry standards required under the solicitation and contract will be required to submit a separate certificate. The information will be used to ensure that the items being purchased meet minimum safety standards and to protect VA employees, VA beneficiaries, and the public.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 559 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One per contract.

Estimated Number of Respondents: 1,118.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–16292 Filed 7–28–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Request for Information on the Department of Veterans Affairs Kinesiotherapist Standard of Practice

AGENCY: Department of Veterans Affairs

ACTION: Request for Information.

SUMMARY: The Department of Veterans Affairs (VA) is requesting information to assist in developing a national standard of practice for VA Kinesiotherapists. VA seeks comments on various topics to help inform VA's development of this national standard of practice.

DATES: Comments must be received on or before September 27, 2022.

ADDRESSES: Comments may be submitted through *www.regulations.gov.* Comments received will be available at *www.regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Ethan Kalett, Office of Regulations, Appeals and Policy (10BRAP), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, 202–461–0500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Authority

38 U.S.C. 73 and 74 and 38 U.S.C. 303 permit the Secretary to further regulate VA's health care professions to make certain that VA's health care system provides safe and effective health care by qualified health care professionals to ensure the well-being of those Veterans who have borne the battle.

On November 12, 2020, VA published an interim final rule to confirm that VA health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification or other requirements that unduly interfere with their practice. 38 CFR 17.419; 85 FR 71838. Specifically, this rulemaking confirmed VA's current practice of allowing VA health care professionals to deliver health care services in a state other than the health care professional's state of licensure, registration, certification or other state requirement, thereby enhancing beneficiaries' access to critical VA health care services. The rulemaking also confirmed VA's authority to establish national standards of practice for health care professionals which would standardize a health care professional's practice in all VA medical facilities.

The rulemaking explained that a national standard of practice describes the tasks and duties that a VA health care professional practicing in the health care profession may perform and may be permitted to undertake. Having a national standard of practice means that individuals from the same VA health care profession may provide the same type of tasks and duties regardless of the VA medical facility where they are located or the state license, registration, certification or other state requirement they hold. We emphasized in the rulemaking, and reiterate here, that VA will determine on an individual basis that a health care professional has the necessary education, training and skills to perform the tasks and duties detailed in the national standard of practice and will only be able to perform such tasks and duties after they have been incorporated into the individual's privileges, scope of practice or functional statement. The rulemaking explicitly did not create any such national standards and directed that all national standards of practice would be subsequently created via policy.

Need for National Standards of Practice

As the Nation's largest integrated health care system, it is critical that VA develops national standards of practice to ensure beneficiaries receive the same high-quality care regardless of where they enter the system and to ensure that VA health care professionals can efficiently meet the needs of beneficiaries when practicing within the scope of their VA employment. National standards are designed to increase beneficiaries' access to safe and effective health care, thereby improving health outcomes. the COVID–19 pandemic underscored the importance of this initiative. With an increased need for mobility in our workforce, including through VA's Disaster Emergency Medical Personnel System, creating a uniform standard of practice better supports VA health care professionals who already practice across state lines. In addition, developing national standards of practice aligns with VA's long-term deployment of a new electronic health record (EHR). National standards of practice are critical for optimal EHR implementation to enable the specific roles for each health care profession in EHR to be consistent across Veterans Health Administration (VHA) and to support increased interoperability between VA and the Department of Defense (DoD). DoD has historically standardized practice for certain health care professionals, and VHA closely partnered with DoD to learn from their experience.

Process To Develop National Standards of Practice

Consistent with 38 CFR 17.419, VA is developing national standards of practice via policy. There will be one overarching National Standard of Practice directive with each individual national standard of practice as an appendix to the directive. The directive and all appendices will be accessible on VHA Publications website at: *https://vaww.va.gov/vhapublications/* (internal) and *https://www.va.gov/vhapublications/* (external) once published.

To develop these national standards, VA is using a robust, interactive process that is consistent with our authority under the Supremacy Clause of the United States Constitution and consistent with the guidance outlined in Executive Order (E.O.) 13132 to utilize such authority. The process includes consulting with internal and external

stakeholders, including State licensing boards.

For each identified VA occupation, a workgroup comprised of health care professionals is established to conduct state variance research to identify internal best practices that may not be authorized under every state license, certification or registration, but would enhance the practice and efficiency of the profession throughout the agency. The workgroup may consult with internal stakeholders at any point throughout the process. If a best practice is identified that is not currently authorized by every state, the workgroup determines what education, training and skills are required to perform such task or duty. The workgroup then drafts a proposed VA national standard of practice using the data gathered during the state variance research and incorporates internal stakeholder feedback to date.

The proposed national standard of practice is internally reviewed, to include review by an interdisciplinary workgroup consisting of representatives from Quality Management; Field Chief of Staff; Academic Affiliates; Associate Director Patient Care Services; Ethics; Workforce Management and Consulting; Surgery; Credentialing and Privileging; Field Chief Medical Office; and Electronic Health Record.

Externally, the proposed national standard of practice is provided to our partners in DoD. In addition, unions are engaged informally as part of a pre-decisional collaboration. We note that the opportunity for bargaining exists later in the process and prior to publication of the national standard. Consistent with E.O. 13132, a letter is sent to each State board that includes the proposed national standard and an opportunity to further discuss the national standard with VA. After the states have received notification, the proposed national standard of practice is published to the **Federal Register** for 60 days to obtain feedback from the public, including professional associations and unions. At the same time, the proposed national standard is published on an internal VA site to obtain feedback from VA employees. Feedback from State boards, the **Federal Register**, VA employees and any other person or organization who informally provides comments will be reviewed. VA will make appropriate revisions based on comments, including those that present evidence-based alternatives that help VA meet our mission and goals, and that are better for Veterans or VA health care professionals. We will publish a collective response to all comments at. *https://www.va.gov/standardsofpractice.*

After the national standard of practice is published and effective, any additional tasks or duties included in the national standard will be incorporated into an individual health care professional's privileges, scope of practice or functional statement only if their VA medical facility performs this function for beneficiaries and the health care professional has the necessary education, training and skill to perform the task or duty.

National Standard for Kinesiotherapists

The proposed structure for national standards of practice when there is a national registration body is as follows: the first paragraph is general information about the profession and what the health care professionals can do at a high level; the second paragraph references the education and credential needed to practice this profession at VA and confirms that this profession follows the standard of practice set by the registration body; and a final statement confirms that as of the date of the workgroup's research into requirements, all individuals in this profession follow the same standard of practice.

We note that proposed standards of practice do not contain an exhaustive list of every task this profession can perform. Rather, it is designed to highlight whether there are any areas of variance in how this profession can practice across states and how this profession will be able to practice within VA notwithstanding their state requirements.

VA qualification standards require Kinesiotherapists to be registered with the Council on Professional Standards for Kinesiotherapy (COPSKT). VA reviewed whether there are any alternative registrations, certifications or state requirements that could be required for a Kinesiotherapist and found that there were none. VA proposes to adopt a standard of practice consistent with this national registration; therefore, Kinesiotherapists will continue to follow the same standard as set by their national registration. The standard of practice for the national registration can be found at *https://akta.org/professional-development/scope-of-practice.*

Proposed National Standard of Practice for Kinesiotherapists

The Kinesiotherapist is an allied health professional competent in the administration of scientifically based musculoskeletal, neurological, ergonomic, biomechanical, psychosocial and task-specific functional tests and measures combined with other evidence-based modalities used to physically, physiologically and psychologically improve the human function, movement and well-being of the Veteran. The Kinesiotherapist provides acute, sub-acute or post-acute rehabilitative therapy and wellness interventions focusing on therapeutic exercise, mobility, reconditioning, education and behavior change emphasizing the psychological as well as physical interventions to enhance outcomes for a holistic approach to rehabilitation.

Kinesiotherapists in VA possess the required education and registration with COPSKT, which is a national board for Kinesiotherapist in accordance with VA qualification standards, as more specifically described in VA Handbook 5005, Staffing, Part II, Appendix G21. This national standard of practice confirms Kinesiotherapists practice in accordance with the American Board of Registration for Kinesiotherapists standards from COPSKT, available at: *https://akta.org/.* As of July 2021, Kinesiotherapists in all States follow this national registration.

Request for Information:

1. Are there any required trainings for the aforementioned practices that we should consider?

2. Are there any factors that would inhibit or delay implementing the aforementioned practices for VA health care professionals in any states?

3. Is there any variance in practice that we have not listed?

4. What should we consider when preempting conflicting state laws, regulations or requirements regarding supervision of individuals working toward obtaining their license or unlicensed personnel?

5. Is there anything else you would like to share with us about this national standard of practice?

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on July 11, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Policy Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2022–16326 Filed 7–28–22; 8:45 am]

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FEDERAL REGISTER

Vol. 87 Friday,
No. 145 July 29, 2022

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.
Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 423, 424, 425, and 455

[CMS–1770–P]

RIN 0938–AU81

Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; updates to conditions of payment for DMEPOS suppliers; HCPCS Level II coding and payment for wound care management products; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act); updates to the Medicare Ground Ambulance Data Collection System; and provisions under the Infrastructure Investment and Jobs Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1770–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1770–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services,Department of Health and Human Services, Attention: CMS–1770–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

Sarah Leipnik, (410) 786–3933, and Anne Blackfield, (410) 786–8518, for issues related to the comment solicitation on strategies for improving global surgical package valuation.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Regina Walker-Wren, (410) 786–9160, for issues related to nurse practitioner and clinical nurse specialist certification by the Nurse Portfolio Credentialing Center (NPCC).

Lindsey Baldwin, (410) 786–1694, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to PFS payment for behavioral health services. *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to PFS payment for evaluation and management services.

Geri Mondowney, (410) 786–1172, Morgan Kitzmiller, (410) 786–1623, Julie Rauch, (410) 786–8932, and Tamika Brock, (312) 886–7904, for issues related to malpractice RVUs and geographic practice cost indices (GPCIs).

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to non-face-to-face nonphysician services/ remote therapeutic monitoring services (RTM).

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment of skin substitutes.

Pamela West, (410) 786–2302, for issues related to revisions to regulations to allow audiologists to furnish diagnostic Tests, as appropriate without a physician order.

Emily Forrest, (202) 205–1922, Laura Ashbaugh, (410) 786–1113, and Erick Carrera, (410) 786–8949, for issues related to PFS payment for dental services.

Heidi Oumarou, (410) 786–7942, for issues related to the rebasing and revising of the Medicare Economic Index (MEI).

Laura Kennedy, (410) 786–3377, and Rachel Radzyner, (410) 786–8215, for issues related to requiring manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds with respect to discarded amounts.

Laura Ashbaugh, (410) 786–1113, and Rasheeda Arthur, (410) 786–3434, for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov,* for issues related to FQHCs.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov,* for issues related to RHCs.

Daniel Feller, (410) 786–6913, and Elizabeth Truong (410) 786–6005, for issues related to coverage of colorectal cancer screening.

Heather Hostetler, (410) 786–4515, for issues related to removal of selected national coverage determinations.

Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Kathleen Johnson, (410) 786–3295, and Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared

Savings Program burden reduction proposal on OHCAs.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment, and financial methodology.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program application, compliance and beneficiary notification requirements.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to vaccine administration services.

Katie Parker, (410) 786–0537, for issues related to medical necessity and documentation requirements for nonemergency, scheduled, repetitive ambulance services.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider enrollment regulation updates (including for skilled nursing facilities), State options for implementing Medicaid provider enrollment affiliation provisions, and conditions of payment for DMEPOS suppliers.

Mei Zhang, (410) 786–7837, and Daniel Standridge, (410) 786–2419, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Medicare Ground Ambulance Data Collection System.

Sundus Ashar, *Sundus.ashar1@cms.hhs.gov,* for issues related to HCPCS Level II Coding for skin substitutes.

Renee O'Neill, (410) 786–8821, or Kati Moore, (410) 786–5471, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2023 PFS proposed rule, refer to item CMS–1770–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov.*

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are a copyright of 2020 American Medical Association (AMA); all rights reserved; and CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

This major annual rule proposes to revise payment polices under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021), Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that we establish each year by regulation the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2023 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this proposed rule addresses:

- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Determination of Malpractice Relative Value Units (RVUs) (section II.H.)
- Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services (section II.I.)
- Payment for Skin Substitutes (section II.J.)
- Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order (section II.K.)
- Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services (section II.L.)
- Rebasing and Revising the Medicare Economic Index (MEI) (section II.M.)
- Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940) (section III.A.)

- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests (section III.C.)
- Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers (section III.D.)
- Removal of Selected National Coverage Determinations (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services (section III.I.)
- Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (section III.J.)
- State Options for Implementing Medicaid Provider Enrollment Affiliation Provision (section III.K.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.L.)
- Medicare Ground Ambulance Data Collection System (GADCS) (section III.M.)
- Proposal to Revise HCPCS Level II Coding Procedures for Wound Care Management Products (section III.N.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine

surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2023 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget

neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

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TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- Payment modifiers: Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work RVUs: The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.
usage = variable, see discussion below in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different

types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 3.

TABLE 3: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2023.

3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)

For CY 2023, as explained in detail in section II.M. of this proposed rule, we are proposing to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. The MEI is an index that measures changes in the market price of the inputs used to furnish physician services. This index measure was authorized by statute and is developed by the CMS Office of the Actuary. We believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, PE and malpractice. Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the MEI. In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs and the CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments to reflect changes in the MEI weights were made for the CY 2014 RVUs, when the MEI was last updated. In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and finalized adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the past when we have proposed a rebasing and/or revision of the MEI, as we do in section II.M. of this proposed rule, we typically have also proposed to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2014 PFS final rule. Instead, we are proposing to delay the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public has an opportunity to comment on the proposed rebased and revised MEI, as discussed in section II.M. of this proposed rule. Because there are significant proposed methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since the last rebasing and revision of the MEI, we believe it is important to allow public comment and

finalization of the proposed MEI changes based on the review of public comment before we incorporate the updated MEI into PFS ratesetting, and we believe this is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the comment solicitation in section II.B. of this proposed rule, where we discuss our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. Similarly, we are delaying the implementation of the proposed rebased and revised MEI for use in the PE geographic practice cost index (GPCI) and soliciting comment on appropriate timing for implementation for potential future rulemaking, discussed in detail in section II.G. and section VII. of this proposed rule.

In light of the proposed delay in using the proposed update to the MEI to make the adjustments to the PE pools in steps 3 and 10 and the relativity adjustment in step 18, we are soliciting comment on when and how to best incorporate the proposed rebased and revised MEI discussed in section II.M. of this proposed rule into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. In section VII. of this proposed rule, we present the impacts of implementing the proposed rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period. Given the significance of the impacts that result from a full implementation and the interaction with other CY 2023 proposals, we did not consider proposing to fully implement a rebased and revised MEI in PFS ratesetting for CY 2023. We are seeking comment on other implementation strategies for potential future rulemaking that are not outlined in section VII. of this proposed rule.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2023 direct PE input public use files, which are available on the CMS website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the

CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2023, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2023, we are proposing to update the price of eight supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2022 PFS final rule. The eight supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 15, CY 2023 Invoices Received for Existing Direct PE Inputs.

We are not proposing to update the price of another eight supplies and two equipment items which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- Acetic acid 5% (SH001): We received an invoice submission for an increase in price from 3 cents per ml to 9.5 cents per ml for the SH001 supply. However, the invoice stated that this price was for an ''Alcian Blue 1% in 3% Acetic Acid pH 2.5'' supply and it is not clear that this represents the same supply as the ''Acetic acid 5%'' described by the SH001 supply item. We also do not believe that the typical price for this supply has increased 200 percent in the 3 years since StrategyGen researched its pricing, especially given that the price for the SH001 supply previously increased from 1.2 cents in CY 2019 to its current price of 3 cents for CY 2022.
- Cytology, lysing soln (CytoLyt) (SL039): We received an invoice submission for an increase in price from 6 cents per ml to 80 cents per ml for the SL039 supply. We do not believe that the typical price for this supply has increased 1200% in the 3 years since StrategyGen researched its pricing, especially given that the price for the SL039 supply previously increased from 3.4 cents in CY 2019 to its current price of 6 cents for CY 2022.
- Fixative (for tissue specimen) (SL068): We received an invoice submission for an increase in price from 1.3 cents per ml to $4.87 for the SL068 supply. We believe that this was the result of confusion on the part of the interested party regarding the unit quantity for the SL068 supply. This item is paid on a per ml basis and not a per unit basis; there was not enough information on the submitted invoice to determine the price for the SL068 supply on a per ml basis.
- Ethanol, 100% (SL189): We received an invoice submission for an increase in price from 0.33 cents per ml to 1.2 cents per ml for the SL189 supply. However, we noted that the invoice was

based on the price for a single gallon of 100% ethanol which is typically sold in much larger quantities than a single gallon. We found that 100% ethanol was readily available for sale online in larger unit sizes and the current price of 0.33 cents per ml (based on the past StrategyGen market research) appears to be accurate based on online bulk pricing. We also found that the submitted invoices for the ethanol, 70% (SL190), ethanol, 95% (SL248), and stain, PAP OG–6 (SL491) supplies were also based on pricing for a single gallon. Each of these supply items was also available for purchase in larger unit quantities which indicated that the current pricing remained typical for these supplies. Therefore, we are not proposing to update the prices for the SL189, SL190, SL248 or SL491 supply, as we do not believe that the higher prices paid for smaller quantities of these supplies would be typical.

- Biohazard specimen transport bag (SM008): We received an invoice submission for an increase in price from 8 cents to 45 cents for the SM008 supply. However, it is not clear that the item described on the invoice is the same item as the SM008 supply. The invoice states only that the price is for ''Supplied Case Red Bags'' which was not enough information to determine if this would be typical for the SM008 supply. We also do not believe that the typical price for this supply has increased 460 percent in the 3 years since StrategyGen researched its pricing, especially given that the price for the SM008 supply previously increased from 3.5 cents in CY 2019 to its current price of 8 cents for CY 2022.
- International Normalized Ratio (INR) analysis and reporting system w-software (EQ312): We did not receive an invoice for this equipment item, only a letter stating that the cost of the EQ312 equipment should be increased from the current price of $19,325 to $1,600,000. We previously finalized a policy in the CY 2011 PFS final rule (75 FR 73205) to update supply and equipment prices through an invoice submission process. We require pricing data indicative of the typical market price of the supply or equipment item in question to update the price. It is not sufficient to state a different price without providing information to support this new valuation. Since we did not receive an invoice to support the higher costs asserted in the letter, we are not proposing a new price for the EQ312 equipment item. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.* We also note that in order to be considered a direct PE input, an equipment item must be individually allocable to a particular patient for a particular service. Costs associated with the implementation, maintenance, and upgrade of equipment that is not individually allocable to a particular patient for a particular service, or other costs associated with running a practice, would typically be classified as forms of indirect PE under our methodology.

The same interested parties that addressed the pricing of the EQ312 equipment item questioned the assignment of the General Practice specialty crosswalk for indirect PE for home Prothrombin Time (PT)/INR monitoring services. These individuals stated that the predominant code used for PT/INR monitoring (HCPCS code G0249) will be significantly and negatively impacted by the continuing implementation over a 4-year period of changes in the clinical labor rates finalized in the CY 2022 PFS final rule (86 FR 65024). The individuals requested that CMS change the crosswalk for home PT/INR monitoring services to All Physicians or Pathology which would partially offset the reduction that HCPCS code G0249 is facing due to changes in the clinical labor rates.

We note for these interested parties that we finalized a crosswalk to the General Practice specialty for home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250) in the CY 2021 PFS final rule (85 FR 84477 and 84478). The data submitted by the commenters at the time indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We disagree, as we did in response to comments in the CY 2021 PFS final rule, that these home PT/INR monitoring services should be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment for the services that result from an unrelated policy proposal (the clinical labor pricing update). We also note that we have not received any new information about PT/INR monitoring services since CY 2021 to indicate that All Physicians or Pathology would be more accurate choices for use in indirect PE allocation but are open to receiving new relevant information that CMS could consider in future rulemaking. As such, we are not proposing to change the assigned specialty for PT/INR services; we direct interested parties to the previous discussion of this topic in the CY 2021 PFS final rule (85 FR 84477 and 84478) and again in the CY 2022 PFS final rule (86 FR 65000). Interested parties are encouraged to submit new information to support the most accurate specialty choice to use in indirect PE allocation for PT/INR monitoring services distinct from what has previously been reviewed during the last two rule cycles.

- Remote musculoskeletal therapy system (EQ402): We received an invoice submission for a price of $1,000 for the EQ402 equipment item. Since this equipment already has a price of $1,000 we are not proposing to make any changes in the pricing; we thank the interested party for their invoice submission confirming the current price.

(1) Invoice Submission

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 4.

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TABLE 4: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Update Proposals

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we are proposing this $0.64 rate for the L037B clinical labor type for CY 2023; we are also proposing a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We are also proposing the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032). The proposed pricing increase for these three clinical labor types is included in Table 5; the CY 2023 pricing for all other clinical labor types would remain unchanged from the pricing finalized in the CY 2022 PFS final rule.

TABLE 5: CY 2023 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.380	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.440	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.360	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.473	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.405	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.565	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.430	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.450	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.455	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.500	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.517	62%
L041A	Angio Technician	L035A	0.41	0.58	0.503	45%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.520	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.520	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A	Mammography Technologist	BLS 29-2034	0.43	0.63	0.530	47%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.670	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.575	56%
L046A	CT Technologist	BLS 29-2035	0.46	0.76	0.610	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.615	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.585	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.585	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.713	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.695	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
L051C	RN/CORF	L051A	0.51	0.76	0.635	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.665	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.660	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.725	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.685	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.800	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.709	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.770	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.298	41%
L152A	Medical Physicist	AAPM Data	1.52	2.14	1.832	41%

* Updated for CY 2023

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of

the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 PFS final rule in response to information provided by commenters. We welcome additional feedback on clinical labor pricing from commenters in response to this proposed rule, especially any data that will continue to improve the accuracy of our final pricing. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

5. Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

The PE inputs used in setting PFS rates, including both the development of PE RVUs and, historically, the relative shares among work, PE, and malpractice RVUs across the PFS, are central in developing accurate rates and maintaining appropriate relativity among PFS services and overall payment among the professionals and suppliers paid under the PFS. Consequently, the underlying PE data inputs are a consistent point of interest among interested parties. However, unlike other payment systems with cost reporting systems, PFS data inputs are primarily based on exogenous proprietary data that become available as the data are collected. Specifically, we rely on historical survey data (almost all of which is over a decade old), some publicly available data collected for other purposes (for example, Bureau of Labor Statistics (BLS) wage data), recommendations from the American Medical Association and other provider groups, and annual Medicare claims data.

a. History of Updates to PE Inputs

Each year we continue to improve accuracy, predictability, and sustainability of updates to the PE valuation methodology to reduce the risks of possible misvaluation and other unintended outcomes. We have continued to develop policies geared toward providing more consistent updates to the direct PE inputs used in PFS ratesetting, including supply/equipment pricing and clinical labor rates. These efforts to develop these policies should contribute to improved standardization and transparency for all PE inputs used to update the PFS. As we continue our work to improve the information we use in our PE methodology, we are issuing a general comment solicitation to better understand how we might improve the collection of PE data inputs and refine the PE methodology.

In recent years, we have refined specific PE data inputs using a combination of market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Last year, we implemented a final transition year for supply and equipment pricing updates and started the first year of a 4-year phase-in update to the clinical labor rates. However, the indirect PE data inputs remain tied to legacy information that is well over a decade old. To build on much needed progress, we now believe indirect PE would also benefit from a refresh that implements similar standard and routine updates. We believe that a data refresh, and use of data sources that receive routine refreshes, would reduce the likelihood of unpredictable shifts in payment, especially when such shifts could be driven by the age of data available rather than comprehensive information about changes in actual costs.

b. Data Collection, Analysis and Findings

In light of feedback from interested parties, CMS has prioritized stability and predictability over ongoing updates, and has taken a measured approach to updating PE data inputs. We have worked with interested parties and CMS contractors over a period of years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear, but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology. Thus, we must balance the various interests of the public, and any path forward should allow for ongoing and routine cycles of PE updates.

Of the various PE data inputs, we believe that indirect PE data inputs, which reflect costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability into our methodology to update PE data inputs. The primary source for indirect PE information is the Physician Practice Information Survey (PPIS), fielded by the AMA. The survey was most recently conducted in 2007 and 2008 (reflecting 2006 data). The survey respondents were self-employed physicians and selected nonphysician practitioners.

In general, interested parties have expressed the following concerns regarding CMS's approach to indirect PE allocation:

- CMS seems to rely on increasingly out-of-date data sources, and there is a dearth of mechanisms to update empirical inputs.
- The approach exacerbates payment differentials that possibly create inappropriate variation of reimbursement across ambulatory places of service (for example, significantly higher payments for the same service provided in a hospital outpatient department versus a physician office).
- CMS's method of indirect PE allocation may not accurately reflect variation in PE across different types of services, different practice characteristics, or evolving business models.

Beyond these issues, we have also explored other concerns with our indirect PE allocation method in depth in previous rulemaking. For example, refer to our previous comment solicitation and discussion of resource costs for services involving the use of innovative technologies in our CY 2022 PFS proposed rule (86 FR 39125). PE data inputs, and the methodological and evidence-based principles that shape use of such information in the context of reimbursement, are discussed in depth in a RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html*.[1]

Various interested parties have taken issue with the use of certain costs in our current PE allocation methodology that they do not believe are associated with increased indirect PE. Some interested parties argue that the costs of disposable supplies, especially expensive supplies, and equipment are not relevant to allocating indirect PE; or that similarly, work in the facility setting (for example, work RVUs for surgical procedures) is not relevant to allocating indirect PE, though they agree that work in the office setting may be relevant to allocating indirect PE. [2] However, we do not believe that there is sufficient, if any,

[1] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

[2] Kazungu, Jacob S., Edwine W. Barasa, Melvin Obadha, and Jane Chuma. ''What Characteristics of Provider Payment Mechanisms Influence Health Care Providers' Behaviour? A Literature Review.'' *The International Journal of Health Planning and Management* 33, no. 4 (October 2018): e892–905. *https://doi.org/10.1002/hpm.2565.*

data or peer-reviewed evidence available to definitively show that shifting indirect PE allocations based on the setting of care, or based on specialty, would result in improved allocations of PE that reflect true costs. Further, varying indirect PE allocations based on setting of care or based on specialty might create unintended consequences such as reduced access to care for beneficiaries, or reduced competition and autonomy of small group practices or individual clinicians whose revenue is based in part on services furnished under contract in the facility setting.

We believe it is necessary to establish a roadmap toward more routine PE updates, especially because potentially improper or outdated allocation of PE across services may affect access to certain services, which could exacerbate disparities in care and outcomes. Establishing payments that better reflect current practice costs would mitigate possible unintended consequences, such as labor market distortions due to indirect cost allocations that do not reflect the current evolution of health care practice.[3] Interested parties have reiterated their desire for CMS to move away from the current PE allocation approach and continued to raise concerns with CMS's methodology and the underlying PE data inputs. In response to these and other concerns, we continue to review the methodology we use to establish the PE RVUs and to identify refinements. As part of this effort, we have contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.[4]

In this proposed rule, we are signaling our intent to move to a standardized and routine approach to valuation of indirect PE and we welcome feedback from interested parties on what this might entail, given our discussion above. We would propose the new approach to valuation of indirect PE in future rulemaking.

We seek comment on the following topics related to identification of the appropriate instrument, methods, and timing for updating specialty-specific PE data:

- Potential approaches to design, revision, and fielding of a PE survey that foster transparency (for example, transparency in terms of the methods of survey design, the content of the survey instrument, and access to raw results for informing PFS ratesetting); and
- Mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations.

We also seek comment on any alternatives to the above that would result in more predictable results, increased efficiencies, or reduced burdens. For example:

- Use of statistical clustering or other methods that would facilitate a shift away from specialty-specific inputs to inputs that relate to homogenous groups of specialties without a large change in valuation relative to the current PE allocations.
- Avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences.
- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE.
- A standardized mechanism and publicly available means to track and submit structured data and supporting documentation that informs pricing of supplies or equipment.
- Sound methodological approaches to offset circularity distortions, where variable costs are higher than necessary costs for practices with higher revenue.

We also seek comment on the cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment). We ask that commenters address the following:

- Whether CMS should stagger updates year-to-year for each update, or establish ''milestone'' years at regular intervals during which all direct PE inputs would be updated in the same year.
- The optimal method of phasing in the aggregate effect of adjustments, such that the impacts of updates gradually ramp up to a full 100 percent over the course of a few years (for example, 25 percent of the aggregate adjustment in Year 1, then 50 percent of the aggregate adjustment in Year 2, etc.).
- How often CMS should repeat the cycle to ensure that direct PE inputs are based on the most up-to-date information, considering the burden of data collection on both respondents and researchers fielding instruments or maintaining datasets that generate data.

c. Changes to Health Care Delivery and Practice Ownership Structures, and Business Relationships Among Clinicians and Health Care Organizations

Market consolidation, and shifts in workforce alignment, as well as an evolution in the type of business entities predominant in health care markets, all suggest significant transformation in the composition and proportions of practice expenses required to furnish care. These evolving conditions collectively highlight the need for a comprehensive update to PE data inputs, and possibly the PE methodology as a whole.[5] Ideally, more comprehensive PE data inputs and a different PE calculation methodology would better account for indirect/overhead costs, current trends in the delivery of health care, the use of machine learning technology, and EHRs, and the cost differentials in independent versus facility-based practices.

We seek comment on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. We are interested in learning whether any PE data inputs may be obsolete, unnecessary, or misrepresentative of the actual costs involved in operating a medical practice.

d. Unintended Consequences and Missing Information

We request comment on additional information that we may have not considered or discussed above about updating and maintaining PE data inputs, as well as any unintended impacts (or positive outcomes) that could result from changes to the overall strategy. We are especially interested in public comment on any concerns about beneficiaries' access to care, possible consolidation of group practices, or burden on small group or solo practitioners. We are also interested in public comments on any collateral

[3] Laugesen, Miriam J. ''Regarding 'Committee Representation and Medicare Reimbursements: An Examination of the Resource-Based Relative Value Scale.' '' *Health Services Research* 53, no. 6 (December 2018): 4123–31. *https://doi.org/10.1111/1475-6773.13084.*

[4] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

[5] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

program integrity or quality issues that could arise from potential updates. We request that any respondents who provide feedback ensure that the response includes discussion of any possible health equity impacts.

6. Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

In preparation for future rulemaking, we are seeking public comment on strategies to improve the accuracy of payment for the global surgical packages (herein referred to as ''global packages') under the PFS. Currently, there are over 4,000 physicians' services paid as global packages under the PFS. Global packages generally include the surgical procedure and any services typically provided during the pre- and postoperative periods (including evaluation and management (E/M) services and hospital discharge services). There are three types of global packages:

- The 0-day global package, which includes the procedure and the preoperative and postoperative physicians' services on the day of the procedure.
- The 10-day global package, which includes services on the day of, and 10 days after, the procedure.
- The 90-day global package, which includes services furnished one day prior to the procedure, and on the day of, and 90 days immediately following the day of the procedure.

More detail about how global packages are billed and what activities are included may be found in Chapter 12, Section 40, of the Medicare Claims Processing Manual (Pub. 100–04).

We have applied the concept of global payment for some procedures since the inception of the PFS on January 1, 1992 (54 FR 59502). However, in the past decade we have engaged with interested parties regarding numerous concerns about the accuracy and validity of the valuation of global packages, with particular attention paid to the E/M visits included in the services. We have made previous requests for public feedback on global packages, including solicitations for information or data that could be used to help support more accurate valuations. We now wish to expand on our conversations with the public, considering the current status of a multi-year data collection and analysis project, as well as ongoing changes we have made to payments for other types of patient care that may impact the global packages.

a. History of Global Valuation Discussion

In the CY 2013 PFS proposed rule (77 FR 44737 through 44738), we discussed two reports released by the HHS Office of the Inspector General in 2005 and 2012 with findings that practitioners were performing fewer E/M postoperative visits than had been included in the valuation for these global packages, suggesting that Medicare was paying for care that was not being delivered. In response to the concerns raised by the OIG reports, we solicited public feedback on methods of obtaining accurate and current data on E/M services furnished as part of a global package. We summarized public comment in the CY 2013 PFS final rule (77 FR 68911 through 68913).

In the CY 2015 PFS proposed rule (79 FR 40341), we delved into barriers to accurate valuation of global packages, especially as compared to other forms of bundled payments made under the inpatient or outpatient prospective payment systems. In addition to the ongoing concerns about whether E/M visits presumed to be furnished in connection with global packages were actually being performed by the physician receiving the global package payment, we noted issues such as:

- E/M services in the global period that occur post-discharge are valued with practice expense values associated with follow-up visits in the physician's office. Many of these follow-up visits may occur in a hospital outpatient department where the physician may not incur many PE costs.
- The direct PE inputs often differ slightly between an E/M service furnished in a global period and a stand-alone E/M service. For example, follow-up visits for certain surgeries may include specialized clinical labor such as an RN rather than a general nurse blend.
- The types of physicians furnishing a specific service dictate the direct and indirect percentages, as well as the indirect practice cost index, in the PE methodology. Most surgical specialties have a lower direct percentage mix, resulting in higher indirect costs that extend to the E/M visits in the global periods.
- Because the E/M visits embedded in the global package are not reported separately and do not appear in claims data, it is difficult to quantify the number and level of E/M services furnished in connection with global packages under the fee-for-service system.
- In some cases we have limited billing of the 10- and 90-day global packages in conjunction with some of the payment policies intended to encourage coordination of care through payments for non-face-to-face services, such as transitional care management and chronic care management, because of presumed overlap between these services.

To address these concerns, we solicited comment and finalized a policy in the CY 2015 PFS final rule (79 FR 67586) intended to, over a period of several years, transition all services with 10-day and 90-day global periods to 0-day global periods. As stated in the CY 2015 PFS final rule, we believed it would be more accurate to value the surgical procedure-day services separately from postop E/M visits, and would avoid potentially duplicative or unwarranted payments. For our full discussion and rationale, refer to 79 FR 67586 through 67591. Implementation of this policy, however, was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L.110–14). Section 523(a) of the MACRA amended section 1848(c)(8) of the Act to prohibit the Secretary from implementing the transition policy finalized in the CY 2015 PFS final rule. The amendments to section 1848(c)(8) also require CMS to collect additional data on how best to value global packages and to reassess every 4 years the continued need for this data collection. Section 1848(c)(8) of the Act directs CMS to use the information collected to improve the accuracy of valuation of these services under the PFS starting in CY 2019. (Refer to the CY 2016 PFS final rule at 80 FR 70915 for additional discussion of these requirements.)

In response to the statutory requirements as added by section 523(a) of the MACRA, we engaged in multiple discussions with interested parties about methods of data collection and analysis, including through public comment solicitation in the CY 2016 PFS proposed rule (80 FR 41707) and CY 2017 PFS proposed rule (81 FR 46191), a national listening session, and a town hall meeting. (Materials for the January 20, 2016 listening session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-01-20-MCRA-Presentation.pdf.* The transcript of the town hall meeting held August 25, 2016 is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2017-PFS-FR-Townhall.pdf.*) In the CY 2017 PFS final rule (81 FR 80209 through 80213), we finalized a claims-based process to collect data from practitioners on both

the number and level of postoperative visits furnished as part of the 10- and 90-day global packages. We also contracted with RAND to support this data collection and analysis.

b. Data Collection, Analysis, and Findings

In 2019, RAND issued two reports based on its analysis of the data collected through the data collection process we established. The reports examined, using claims-based and survey-based data, the number of postoperative visits furnished during the 10- and 90-day global periods for certain high-volume procedures and the level of visits furnished for certain procedures. (Complete details about the data collected are discussed in the CY 2017 PFS final rule starting at 81 FR 80212, the CY 2020 PFS final rule at 84 FR 62857, and in the reports themselves, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*.) Notably, RAND's analysis found that, according to claims-based data, the reported number of E/M visits matched the expected number (included for purposes of PFS valuation) for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. Based on these analyses, RAND released a third report that analyzed the current valuation of global packages based on the difference between the number of postoperative E/M visits observed via the claims-based data collection process and the expected number of such E/M visits. The report modeled how valuation for global packages would change by adjusting the work RVUs, physician time, and direct PE inputs to reflect the observed number of E/M visits. The report provided hypothetical valuations for the global packages based on these adjustments. These three RAND reports were made available to the public and are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*.

The RAND reports were shared with the public, and we received public comment about these reports in the CY 2020 PFS final rule (84 FR 62866). Public commenters raised concerns about the findings in the reports, including questions as to whether the E/M visit data were collected from a true representative sample of practitioners, and various other challenges to the validity of the RAND methodology. Other members of the public, however, were supportive of our overall efforts to collect and analyze the data, and supplied additional data similarly suggesting that the 10- and 90-day global packages are overvalued. In 2021, RAND responded to the CY 2020 public comments that were critical of the methodologies used in the three earlier reports in a separate report entitled, ''Responses to Comments on RAND Global Services Reports,'' which is available at *https://www.rand.org/content/dam/rand/pubs/research_reports/RR4300/RR4314-1/RAND_RR4314-1.pdf/*.

While some interested parties have challenged the methodology or conclusions of the RAND reports, we have not yet received data suggesting that postoperative E/M visits are being performed more frequently than indicated by the data collected and analyzed in the RAND reports. We continue to be concerned that our current valuations of the global packages reflect certain E/M visits that are not typically furnished in the global period, and thus, are not occurring. We also believe that RAND has adequately responded to critiques of its methodologies and findings. However, as part of our ongoing assessment of our data collection process, we continue to welcome any comments from the public on ideas for other sources of data that would help us to assess global package valuation (including the typical number and level of E/M services), as well as our data collection methodology and the RAND report findings.

c. Changes to Health Care Delivery and Payment for E/M Services

Since the inception of the PFS 30 years ago, there have been significant changes in health care, including improvements in medical and information technology, new models of health care delivery and coordination between multiple clinicians furnishing care to a single patient, and an expanding beneficiary population. (For information on Medicare service utilization, beneficiary demographics, provider characteristics, and payment models, please visit the resources at *data.cms.gov*.) We are interested in hearing from the public on whether the postoperative health care landscape has changed in ways that impact the relevance of the global packages.

We believe that changes to health care delivery may impact proper valuation of global services. We are soliciting comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past 3 decades, as well as during the recent PHE, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care. We have formed hypotheses that some beneficiaries are not receiving the number of postoperative visits that were contemplated when valuing the global surgical packages or are not receiving any follow-up E/M visits at all during global periods either because the physician who performed the surgical procedure has determined they are unnecessary (perhaps due to improvements in medical technology or evolution in standards of care) or as the result of more comprehensive discharge planning. It has also been suggested by some interested parties that physicians are, in fact, performing the number of postoperative visits that were contemplated when valuing the global surgical packages, but the visits may, for various reasons, be scheduled outside the global period. Others have suggested that physicians are, without formally transferring follow-up care to another clinician, instructing patients to follow up with another physician or NPP (such as the patient's primary care physician or other practitioner), and that the other clinician then furnishes and bills for E/M services furnished for postoperative care (whether the care is performed during or after the global period). We would appreciate comments on these ideas, and on other factors not mentioned here that could affect the ways that postoperative E/M care is provided.

We are also soliciting comment on whether, or how, recent changes in the coding and valuation of separately billable E/M services may have impacted global packages. One change is the expansion of payment for non-face-to-face care management services. Historically, an advantage of global packages was that they compensated physicians for non-face-to-face work related to the patient's transition from the hospital to the community, or management of other health care needs following a procedure or serious illness. Over the years, we have implemented payment for many care management services to better reflect non-face-to-face time spent by physicians and clinical staff on behalf of patients with complex health care needs, including transitional care management services in CY 2013 (77 FR 68978); chronic care management in CY 2015 (78 FR 74414) and CY 2019 (83 FR 58577); complex chronic care management in CY 2017 (81 FR 80244); and principal care management in CY 2020 (84 FR 62962).

We solicit comment on whether global packages, and especially those with 10- and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately not only for the postoperative E/M visits they furnish, but also for aspects of postoperative care management they furnish for some patients. We also would like to hear generally what, if any, components of preoperative or postoperative care are currently only compensated as part of payment for global packages.

We have also heard from some interested parties who believe that recent changes to the coding and valuation of standalone office and outpatient E/M visits finalized in the CY 2021 PFS final rule have skewed the relativity between these visits and the E/M visits included in the current global package valuations (which were not modified in response to the coding and valuation changes). In the CY 2020 PFS final rule (84 FR 62851 through 84 FR 62854), we finalized new—and generally increased, RVUs for the CPT-revised office and outpatient E/M code set. Some commenters encouraged us to increase the value of the E/M visits included in the global surgical packages commensurate with the increased RVUs for the standalone E/M visits. However, we declined to do so, noting that at the time that it was unclear whether it would be appropriate to treat the E/M visits reflected in global packages as discrete components of the package (in other words, to use a building-block approach to calculating the value of the service, versus valuing the services using the more holistic magnitude estimation, or possibly another approach.) Furthermore, we cited the uncertainty as to whether the E/M services included in valuing the global packages are typically furnished as part of global surgery services, reasoning that if the number and level of E/M services for global packages is not appropriate, adopting increases in the value of E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues. (Refer to the CY 2020 PFS final rule at 84 FR 62856 through 62860 for a complete summary of comments and our responses on the topic of increasing the value of E/M visits included in the global packages.) We welcome additional comments on the perceived misalignment between the E/M visits included in global packages and separately billable E/M services, including thoughts on how this current tension reflects on global payment valuation and the appropriate methodology for determining appropriate values for global packages.

d. Strategies To Address Global Package Valuation

Consistent with the discussion above, we continue to believe that: (1) there is strong evidence suggesting that the current RVUs for global packages are inaccurate; (2) many interested parties agree that the current values for global packages should be reconsidered, whether they believe the values are too low or too high; and (3) it is necessary to take action to improve the valuation of the services currently valued and paid under the PFS as global surgical packages.

We would like to re-engage with the public about whether the global packages are indeed misvalued, and if so, what would be an appropriate approach to valuation. We have previously sought assistance from the public on possible methods of revaluation, such as in the CY 2015 PFS rule (at 79 FR 67586).

As noted in the ''Data Collection, Analysis, and Findings'' section above (section II.B.6.b.), RAND has provided a comprehensive roadmap for a possible revaluation strategy. (See specifically the RAND report, ''Using Claims-Based Estimates of Postoperative Visits to Revalue Procedures with 10- and 90-Day Global Periods,'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*) We are soliciting additional input on the RAND methodology, including advantages and drawbacks of applying the RAND methodology to revaluation (in addition to previous feedback that was provided by the public in the CY 2020 final rule at 84 FR 62867). We also request input on specific alternatives, including: (1) requesting the RUC to make recommendations on new values; or (2) another method proposed by the public.

We solicit feedback from the public on possible strategies for a revaluation process for global services. We believe that the available information provided in the RAND reports (discussed in section II.B.6.b. of this proposed rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*) indicates that there is a mismatch between the value of the global package and work being performed. In particular, it appears that for some services, the number of postoperative visits typically furnished by the billing physician is much lower than what was reflected in the global package value, and thus we believe it may be necessary to revalue those services. (As noted in section II.B.6.b. of this proposed rule, RAND's analysis found that the reported number of E/M visits matched the expected E/M visits for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. We refer specifically to the RAND report, ''Claims-Based Reporting of Postoperative Visits for Procedures with 10- or 90-Day; Global Periods—Updated Results Using Calendar Year 2019 Data'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*). Because there are a large number and volume of services paid as global packages, we must consider the resources needed to revalue even a subset of the global packages, as well as the impacts across the PFS and healthcare delivery system in general if we were to change the values of a significant number of services at one time. We are considering various approaches we could pursue, such as: (1) revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates); (2) revaluing only the 10-day global packages (because these appear to have the lowest rate of postoperative visit performance, per RAND's analysis of claims data); (3) revaluing 10-day global packages and some 90-day global packages (such as those with demonstrated low postoperative visit performance rates as identified in RAND's analysis of these services); or (4) relying on the Potentially Misvalued Code process to identify and revalue misvalued global packages over the course of many years. (We note that regardless of whether we review particular global packages as part of a specific revaluation strategy, the public may always nominate any global packages to be reviewed through the Potentially Misvalued Code process; refer to the description of the Potentially Misvalued Code process in section II.C. of this proposed rule.) We solicit comment on any of the strategies identified in this paragraph, as well as any additional ideas members of the public may have that would address the concerns described above about valuation of global packages. We also welcome comment on ancillary considerations including timing considerations for implementation of any future strategy (such as whether to have staggered effective dates for new valuations and what criteria to use if assigning staggered effective dates.)

We also solicit comment on additional considerations affecting valuation of global services that may not have been thoroughly explored in

previous public comment opportunities. For instance, we are aware that some interested parties are concerned that not enough attention has been paid to the value of preservice work bundled into the global payment, which could affect accurate valuation of 10- and 90-day global packages, as well as the value of the service if it is transitioned to a 0-day global. We solicit additional information about this concern, as well as any other concerns about valuation not otherwise mentioned here.

e. Other Payment Structure Changes, Unintended Consequences, and Missing Information

We solicit public comment on any other aspects of the global payment structure (aside from the valuation of services) that commenters believe are noteworthy. Much of the discussion over the years has focused on whether global surgical packages are properly valued and whether they are needed at all. We encourage commenters to point out ways in which global surgical packages may continue to have a positive impact on health care delivery (such as their potential to support innovation). We also solicit suggestions on other ways that global surgical package payments could be modified (aside from changing their valuation) that could help improve accurate valuation or help address other concerns about the payments (such as the lack of transparency about what care is being provided as part of the package).

We also request comment on additional information that we may not have considered or discussed above about proper valuation of the global packages, as well as any unintended impacts (or positive outcomes) that could result from changes to how we value global services. We are especially interested in public comment on any concerns about beneficiaries' access to care, continuity of care, cost sharing, or program integrity.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this proposed rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.

- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov,* with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897) we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2023 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and

organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We received public nominations for potentially misvalued codes by February 10th and we displayed these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. Some submissions are for specific, PE-related inputs for codes, and we refer readers to section II.B. of this rule under Determination of PE RVUs for further discussions on PE-related submissions. We summarize below this year's submissions under the potentially misvalued code initiative.

An interested party nominated the home-based physician visit codes: CPT code 99344 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family*), CPT code 99345 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family*), CPT code 99349 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family*), and CPT code 99350 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family*) as potentially misvalued.

In their submission, the nominator expressed concern that there is no payment for transportation costs incurred when it is medically necessary for a physician to drive to the home of the patient for a face-to-face in-home E/M Visit, and that they are not compensated for opportunity loss they incur by seeing fewer patients because they spend time commuting to patients' homes, versus seeing more patients that come to their offices. The nominator also argued that Medicare does not compensate physicians for the work and time associated with assessing a patient's home environment, which provides insight into a patient's overall health and living conditions. The nominator collectively called these non-medical factors that can affect a patient's overall health the ''Social Determinants of Health'' (SDoH). The nominator requested that we increase the overall RVUs for CPT codes 99344, 99345, 99349, and 99350, by including the resources associated with: (1) the physician's transportation costs to patients' homes; (2) lost income opportunity for home versus in-office visits; and (3) in-home SDoH assessment work. The nominator estimated that the adjustments to RVUs to reflect transportation costs and opportunity costs would result in Medicare payment that is 67 percent higher than the current Home-based E/M Visits payment rates, and that adjustments to account for the physician's SDoH assessment would add an additional 55 percent increase to the payment rates for Home-based E/M Visits. In total, the nominator suggests that if these resources were taken into account, the payment rates for Home-based E/M CPT codes would increase by what the nominator estimates as a 222 percent increase from their current amounts.

The nominator included references as evidence to support their claim that the home-based E/M CPT codes are potentially misvalued, such as the CMS ''Medicaid Non-Emergency Medical Transportation Booklet for Providers'' (April 2016) [6] [7] and a press release from the Better Medicare Alliance entitled, ''Report Shows Dramatic Increase in Medicare Advantage Activity to Address Social Determinants of Health, But Barriers Remain''.[8]

We note that the nominator did not nominate the entire family of home-based E/M visit codes.

When we establish values for codes or consider whether codes are potentially misvalued under the PFS, we take into account the resources involved in furnishing the specific service as described by the CPT code. As such, historically, we do not take into account: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in one setting versus another; or (3) the physician or other practitioner's work and time expended in performing activities that are outside the scope of the specific service as described by the CPT code. These are not considered to be resources involved in furnishing the service, are not included in establishing payment rates under the PFS in accordance with

[6] *https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nemt-booklet.pdf.*

[7] *https://storage.aanp.org/www/documents/NP-Infographic.pdf.*

[8] *https://bettermedicarealliance.org/news/report-shows-dramatic-increase-in-medicare-advantage-activity-to-address-social-determinants-of-health-but-barriers-remain/#:~:text=Social%20determinants%20of%20health%20are,to%20the%20World%20Health%20Organization.*

section 1848 of the Act, and, as such, do not provide justification for potential misvaluation of those payments. That said, in February 2021, the AMA CPT Editorial Panel deleted the family of domiciliary codes, CPT codes 99324 to 99340, and merged the services described by those codes into the existing family of home-based E/M visits, CPT codes 99341 to 99350 (a range of codes that includes CPT codes 99344, 99345, 99349, and 99350). In addition, the AMA RUC has made recommendations regarding the values for these home-based E/M codes in section II.E. of this proposed rule. Since CMS has already received AMA RUC recommendations for these home-based E/M visit codes for this year's proposed rule, we refer readers to the discussion found in section II.E. of this proposed rule, Valuation of Specific Codes, where we seek additional public comments, recommendations, and independent analysis as supporting evidence from all interested parties regarding the valuations for the home-based E/M visits, including CPT codes 99344, 99345, 99349, and 99350. Because we address and are soliciting public comment on the valuation of these codes in section II.E. of this proposed rule, there is no need to consider these home-based E/M visits here as potentially misvalued.

An interested party has nominated the following cataract surgery codes, CPT codes 65820 (*Goniotomy—Incision to improve eye fluid flow*), 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*), 66982 (*Complex Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*), 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)*), 66989 (*Complex Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more*), and 66991 (*Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more*), as well as the following retinal procedure codes, CPT codes 67015 (*Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy)*), 67036 (*Vitrectomy, mechanical, pars plana approach*), 67039 (*Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation),* 67040 (*Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation*), 67041 (*Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (e.g., macular pucker)*), 67042 (*Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (e.g., for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil)*), 67043 (*Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (e.g., choroidal neovascularization), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil) and laser photocoagulation*), 67108 (*Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*), and 67113 (*Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens*), as potentially misvalued because there is currently no established non-facility payment rate for these global 090-day surgical procedures. These codes are complex surgical eye procedures and they require dedicated spaces, similar to facility-based spaces that are not typically found in an ophthalmologist's office, such as a well-lighted and sterile surgical theater, specific eye surgery equipment and possibly clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery, including anesthesia services. In the past, with concerns for patient safety and given the intricate and delicate nature of these surgeries, we understood that these procedures would only be performed in a well-equipped and fully staffed medical facility. This may still be the case, but this nominator suggests that these cataract and retinal procedures can be properly performed in the non-facility office, safely, effectively, and perhaps more conveniently for patients and physicians; and thus requests that we should establish non-facility RVUs under the PFS to recognize the additional resources that would be expended in the non-facility setting.

The nominator has included a list of practice expense items involved in furnishing these services in the non-facility setting to help us to consider establishing non-facility values for these codes. They include the possible number and types of clinical staff and their work time in minutes, and a list of various equipment and supplies typically needed to furnish the services described by the nominated codes.

The nominator also noted that there is projected backlog for these cataract and retinal services that may have been building up due to the COVID–19 restrictions from the past 2 years. We seek comment on the merits of continuing to value these codes only in the facility setting, as opposed to also establishing non-facility values for these cataract and retinal surgery codes. We also seek comment on any appropriate safety considerations for these codes in the non-facility setting and whether these codes are potentially misvalued. We note that in last year's CY 2022 PFS final rule with comment (86 FR 65096 through 65097), we did review CPT codes 66982, 66984, 66987, 66988, 66989, 66991, and 0671T (Cataract Removal *with* Drainage Device Insertion) and did not establish non-facility values for those services, but we did note a potential rank order anomaly when considering minimally invasive glaucoma surgeries (MIGS) and cataract surgeries together, and suggested that the AMA RUC should consider re-surveying all of these.

An interested party has nominated add-on CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*) as a potentially misvalued service with respect to the physician's labor for spinal surgeries involving the use of biomechanical synthetic cage devices versus the use of structural allograft bone as it relates to a set of CPT codes related to anterior cervical discectomy and fusion (ACDF). Ordinarily, interested parties nominate a primary service code as potentially misvalued, or a primary service code and its related add-on codes, but not an add-on code alone. The valuation of an add-on code is typically developed with reference to some portion of the work (or other resource inputs) involved in furnishing the primary service code. For

example, the AMA CPT 2022 Professional Edition, page 147, states ''Use code 20931 in conjunction with codes 22319, 22532–22533, 22548–22558, 22590–22612, 22630, 22633, 22634, 22800–22812''). The primary spinal surgery codes and the add-on CPT code 20931 have not been recently reconsidered or reviewed by the AMA RUC or CMS, and no new or additional information has been included with this nomination to persuade CMS that CPT code 20931 is individually potentially misvalued. This nomination of an add-on code as potentially misvalued is similar to the nomination we discussed in the CY 2022 PFS proposed rule (86 FR 65044) of CPT code 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2*) and the accompanying add-on codes.

The nominator refers to two different methods of vertebral fusion—one using biomechanical synthetic cage devices, the other using structural allograft bone; and describes a typical vertebral fusion case that uses three units of one of these products. Both of these methods of vertebral fusion are described by CPT code 22551 (includes a 90-day global period), which has a work RVU of 25.00. Both methods of vertebral fusion also involve two units of CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*), which have a total work RVU of 13.00 (6.50 × 2), and 1 unit of CPT code 22846 (*Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)*), which has a work RVU of 12.40. The vertebral fusion method employing three synthetic cage devices with plate would involve three units of CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*) for a total work RVU of 12.75 (4.25 × 3), and one unit of CPT code 20930 (*Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)*) with a work RVU of 0.00 (because Medicare considers this code to be bundled into codes for other services). The nominator states that the typical vertebral fusion employing three synthetic cage devices with plate would total to 63.15 work RVUs.

In contrast, the nominator asserts that the vertebral fusion method employing structural allograft bones with plate involves the same set of services and codes (that is, one unit of CPT code 22551, two units of CPT code 22552, and one unit of CPT code 22846), but the structural allograft bone method includes CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*), with a work RVU of 1.81, instead of CPT codes 22853 and 20930, for a total work RVU of 52.21. The nominator suggests that this difference in total work RVUs for the two methods of vertebral fusion, 63.15 versus 52.21, is evidence that add-on CPT code 20931 is potentially misvalued; however, we do not agree with this nominator's method of aggregating and comparing sums of work RVUs for groups of services that may be furnished together as being potentially misvalued, nor consider CPT code 20931 as the source of misvaluation within this grouping.

We understand that the nominator believes there should be an equivalent total sum payment for all services involved in vertebral fusion surgeries using either method, and that there should not be a potential incentive for physicians to prefer the method that uses synthetic cage devices because of the higher available payment amount. The nominator asserts that the total sum payment for this kind of spinal surgery using the structural allograft bone method is undervalued as compared to the total sum payment for this kind of spinal surgery using the synthetic cage method.

We note that CPT code 22853, which the commenter associates with the synthetic cage device method of vertebral fusion, is a 45-minute ZZZ-code (indicating an add-on code) with an IWPUT (intra-service work (RVU) per unit of time) of 0.0944, whereas CPT code 20931, which the commenter associates with the allograph method of vertebral fusion, is a 20-minute ZZZ-code with an IWPUT of 0.0905. Given the much longer intra-service time and greater IWPUT for CPT code 22853 than for CPT code 20931, the allograph method of vertebral fusion would be expected to have a lower total sum of work RVUs.

The nominator's description of why and how each vertebral fusion method is potentially misvalued when compared to the other does not present a situation that fits within our process for identifying individual services that are potentially misvalued using certain criteria, as described in the beginning of this section. Our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to individual codes, or with the inter-code relativity between the RVUs assigned to several individual codes found within a family of codes with hierarchical relationships. CMS generally does not examine the summed differences in total RVUs (as is the case presented here), based on billing patterns for a combination of codes representing differing physician work for different methods of performing a service, and then comparing the total RVUs of each method as evidence of the potential misvaluation of codes. We do not believe that the nominator has provided sufficient evidence to demonstrate that CPT code 20931 itself is misvalued, and therefore, we are not inclined to propose this code as potentially misvalued; however, we seek additional comment and any independent analysis and studies (see the supporting documentation options listed above under ''CY 2023 Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service) as supporting evidence from commenters in agreement or disagreement with this nomination.

See Table 6 for the listing of nominated potentially misvalued codes.

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TABLE 6: Interested Parties' Nominations of CPT Codes as Potentially Misvalued for CY 2023

CPT	CPT Descriptor
Home Visits codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Cataract Surgery codes:	
65820	Relieve inner eye pressure
66174	Translum dil eye canal
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66989	Xcpsl ctrc rmvl cplx insj 1+
66991	Xcapsl ctrc rmvl insj 1+
Retinal Procedure codes:	
67015	Release of eye fluid
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67108	Repair detached retina
67113	Repair retinal detach cplx
Spinal Surgery code:	
20931	Allograft, structural, for spine surgery only (add-on code)

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D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare Telehealth Services List to one of the following two categories:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- Category 2: Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic: Category 3. This new category describes services that were added to the Medicare Telehealth Services List during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio-video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criterion described above. We assessed codes that were temporarily available on the list for the duration of the PHE to determine their appropriateness for inclusion on the Medicare Telehealth Services List on a Category 3 basis. We have reassessed the services that are temporarily available via telehealth for the PHE, based on both information provided by interested parties and our own internal review. We have assessed whether or not these services can, outside of the circumstances of the PHE, be furnished using the full scope of service elements via two-way, audio-video communication technology, without jeopardizing patient safety or quality of care, and we now believe that there are additional services that would be appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis that we did not identify in the CY 2021 rulemaking. In this proposed rule, we are proposing to add these additional services to the Medicare Telehealth Services List on a Category 3 basis, as further discussed below.

The Medicare Telehealth Services List, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2023, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2022. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare Telehealth Services List, including where to submit these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2023

Under our current policy, we add services to the Medicare Telehealth Services List on a Category 1 basis when we determine that they are similar to services on the existing Medicare Telehealth Services List for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criterion not only streamlines our review process for publicly requested services that fall into this category, but also expedites our ability to identify codes for the Medicare Telehealth Services List that resemble those services already on the Medicare Telehealth Services List. We add services on a Category 2 basis when the service does not fall within Category 1, and based upon our assessment of whether the services are accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. We add services on a temporary Category 3 basis when the services were temporarily included on the Medicare Telehealth Services List during the PHE, and we find that there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2023. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. We also assessed the appropriateness of adding these services to the Medicare Telehealth Services List on a Category 3 basis instead.

We are not proposing changes to the length of time the services that we temporarily included on a Category 3 basis will remain on the Medicare Telehealth Services List; the services we temporarily included on the Medicare Telehealth Services List on a Category 3 basis will continue to be included through the end of CY 2023. In the event that the PHE extends well into CY 2023, we may consider revising this policy.

We are proposing to add some services to the Medicare Telehealth Services List on a Category 3 basis through the end of 2023, some of which we had not previously added to the Medicare Telehealth List during the PHE, but will be added on a subregulatory basis as provided in § 410.78(f) of our regulations. For some of these services, we have received information from interested parties suggesting potential clinical benefit. For others, we continue to believe there is sufficient evidence of potential clinical benefit to warrant allowing additional time for interested parties to gather data to support their possible inclusion on the Medicare Telehealth Services List on a Category 1 or 2 basis. The Medicare Telehealth Services List requests for CY 2023 are listed in Table 7.

Additionally, the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) amended section 1834(m) of the Act to extend a number of flexibilities that are in place during the PHE for COVID–19 for 151 days after the end of the PHE. To align the availability of these services with those flexibilities

extended under the Act, we are proposing to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE.

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TABLE 7: Services Requested for Addition to the Medicare Telehealth Services List for CY 2023

HCPCS	Long Descriptor	Basis
	Code Family	
	Lactation classes	
S9443	Lactation classes, non-physician provider, per session	
	Telephone E/M	
99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	3
99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	3
99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	3
	Therapy	
90901	Biofeedback training by any modality	1
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	1
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	1
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	1
97150	Therapeutic procedure(s), group (2 or more individuals)	1
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of	1

HCPCS	Long Descriptor	Basis
	high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.	
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	1
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	1
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes	1
97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes	1
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes	1
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes	1
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes	1
98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	1
98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	1
98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	1
Gastrointestinal tract imaging		
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report	3
Ambulatory continuous glucose monitoring		
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report	N/A
Electronic analysis of implanted neurostimulator pulse generator/transmitter		
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	3
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	3
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters,	3

HCPCS	Long Descriptor	Basis
	and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	
	Adaptive behavior treatment and Behavior identification assessment	
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	2
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	2
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	2
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	2
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	2
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	2
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	2
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	2
0362T	Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2

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We remind interested parties that the criterion for adding services to the Medicare Telehealth Services List under Category 1 is that the requested services are similar to professional consultations, office visits, and/or office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services listed in Table 7 met the Category 1 or 2 criteria.

We received a request to permanently add CPT code S9443 (*Lactation classes, non-physician provider, per session*) to the Medicare Telehealth Services List. This service has a status code of ''I,'' which means that it is not valid for Medicare billing purposes. We understand that this is a temporary code established by a private payor for private payor use, and thus, it is not valid for nor payable by Medicare. As such, this code is not separately billable under the PFS. We generally do not add services to the Medicare Telehealth Services List unless they are separately billable under the PFS. Outside of the circumstances of the PHE, the Medicare Telehealth Services List only includes services that are covered if they are furnished without the use of telecommunication technology in-person. Because CPT code S9443 is not billable under the PFS when furnished in-person, we do not believe it would be appropriate to allow the service to be billed separately when furnished as a Medicare telehealth service. As noted in the CY 2018 PFS final rule (82 FR 53011), if a service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of the statute. We are not proposing to add CPT code S9443 to the Medicare Telehealth Services List.

(1) Therapy Services

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116, 97150, and 97530; Physical Therapy Evaluations: CPT codes 97161–97164; Therapy Personal Care services: CPT codes 97535, 97537, and 97542; and Therapy Tests and Measurements services: CPT codes 97750, 97755, and 97763, to the Medicare Telehealth Services List on a Category 1 basis.

In the CY 2022 PFS final rule (86 FR 65051), we determined that these services did not meet the Category 1 criteria for addition to the Medicare Telehealth Services List because they involve direct observation and/or physical contact between the practitioner and the patient and, in many instances, are therapeutic in nature, and that they did not meet Category 2 criteria, because we thought

that the request did not provide sufficient detail to determine whether all of the necessary elements of the service could be furnished remotely. We continue to believe this is the case. We still do not have sufficient information to determine whether these services meet the Category 2 criteria. However, we note that some of these codes, including codes 97110, 97112, 97116, 97150, 97530, 97161–97164, 97535, 97542, 97750, and 97755 have been added to the list on a temporary basis for the duration of the PHE.

In assessing the evidence that was supplied by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely. Information regarding safety, appropriateness, and that indicates that all elements of a given CPT code can be furnished via telehealth is still needed to assess whether these services meet the Category 2 criteria. However, we also believe that the therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE (including CPT codes 97150, 97530, and 97542), but are not currently included on a Category 3 basis, may continue to be furnished safely via two-way, audio-video communication technology outside of the circumstances of the PHE.

Therefore, we are proposing that CPT codes 97150, 97530, and 97542 (the set of therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE), should be added to the Medicare Telehealth Services List through the end of CY 2023 on a temporary, Category 3 basis, to allow time to gather additional data that could support their inclusion on the list on a permanent basis. Therefore, we are proposing to add CPT codes 97150, 97530, and 97542 to the Medicare Telehealth Services List on a Category 3 basis. CPT codes 97110, 97112, 97116, 97161–97164, 97535, 97750, and 97755 will continue to be available on the Medicare Telehealth Services List on a Category 3 basis. We anticipate that keeping these services on the Medicare Telehealth Services List on a Category 3 basis, as proposed, through the end of CY 2023 would preserve access to care and promote health equity, and based on information provided by interested parties and internal review, we believe that they may safely be furnished as telehealth outside of the circumstances of the PHE through the end of CY 2023. However, we remind readers that the practitioners who primarily furnish these services, physical therapists, are not, outside the circumstances of the PHE (and the 151 day period following the expiration of the PHE), authorized to furnish Medicare telehealth services. We note that if the PHE and the 151 day period following the expiration of the PHE both end in CY 2023, the pre-PHE rules will take effect, and these services could no longer be furnished by therapists as Medicare telehealth services.

Certain other requested therapy services, namely CPT codes 97537, 97763, 90901, and 98960–98962 are not currently on the Medicare Telehealth Services List; however, we are adding these services to the Medicare Telehealth Services List on a temporary basis during the PHE, in accordance with § 410.78(f). As explained below in section II.D.1.d. of this proposed rule, services included on the Medicare Telehealth Services List on a temporary basis during the PHE that have not been added to the list on a Category 3 basis will remain on the list for 151 days following the end of the PHE. Furthermore, we are proposing to add CPT codes 97537, 97763, 90901, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis through the end of CY 2023. Our clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology during the circumstances of the PHE, and information provided by requestors indicates that there may be clinical benefit; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. Including these services on the Medicare Telehealth Services List during the PHE and through CY 2023 would allow additional time for the development of evidence for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List on a Category 1 or 2 basis. We continue to encourage commenters to supply additional information in support of adding these services to the Medicare Telehealth Services List on a permanent basis, including information regarding the safety and appropriateness of furnishing these services via telehealth.

(2) Telephone E/M Services

We have also received requests to temporarily add Telephone E/M visit codes, CPT codes 99441, 99442, and 99443 to the Medicare Telehealth Services List on a Category 3 basis. In the March 31, 2020 interim final rule with comment period (IFC), we established separate payment for audio-only telephone E/M services (85 FR 19264 through 19266) for the duration of the PHE for the COVID–19 pandemic. Although these services were previously considered non-covered under the PFS, in the context of the PHE for COVID–19 and with the goal of reducing exposure risks associated with COVID–19 (especially in situations when two-way, audio and video technology is not available to furnish a Medicare telehealth service), we believed there were circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. In the May 8, 2020 COVID–19 IFC, we noted that interested parties had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not using video-enabled communication technology from their homes. In other words, there were many cases where practitioners who would ordinarily furnish audio-video telehealth or in-person visits to evaluate and manage patients' medical concerns were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE for COVID–19, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the PHE for COVID–19 was not accurately captured by the valuation of these services that we established in the March 31, 2020 IFC (85 FR 27590). This would be particularly true to the extent that these audio-only services are serving as a substitute for office/outpatient (O/O) Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology, which is contrary to the situation we anticipated when establishing separate payment for them in the March 31, 2020 IFC. In the May 8, 2020 COVID–19 IFC, we stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the O/O E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous O/O E/M codes, based on the time

requirements for the telephone codes and the times assumed for valuation for purposes of the O/O E/M codes. Specifically, we crosswalked the levels 2–4 O/O E/Ms for established patients, as described by CPT codes 99212, 99213, and 99214, to CPT codes 99441, 99442, and 99443, respectively. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for O/O E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare Telehealth Services List for the duration of the PHE for COVID–19 (85 FR 27590).

In the CY 2022 PFS final rule (86 FR 65055), in response to requests that these codes be added to the Medicare Telehealth Services List on a Category 3 basis, we stated that we were finalizing a change to the definition of ''telecommunications system'' to allow telehealth services for the diagnosis, evaluation, and treatment of mental health conditions to be furnished through audio-only technology in certain circumstances after the end of the PHE. For example, the O/O E/M codes are on the Medicare Telehealth Services List permanently and when used to describe care for mental health conditions, will be reportable when furnished via audio-only technology to patients in their homes. Since audio-only telecommunications technology can be used to furnish mental health telehealth services to patients in their homes, the addition of these codes to the Medicare Telehealth Services List is unnecessary for mental health telehealth services. For telehealth services other than mental health care, we stated that we believe that two-way, audio-video communications technology is the appropriate standard that will apply for telehealth services after the PHE ends. Further, we note that section 1834(m)(2)(A) of the Act requires that payment to a distant site physician or practitioner that furnishes Medicare telehealth services to an eligible telehealth individual be equal to the amount that would have been paid under Medicare if such physician or practitioner had furnished the service without a telecommunications system. We believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. However, these audio-only telephone E/M services are inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications. Outside the circumstances of the PHE, the telephone E/M services would not be analogous to in-person care; nor would they be a substitute for a face-to-face encounter. Therefore, we do not believe it would be appropriate for these codes to remain on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE extension period. Accordingly, we are not proposing to keep these telephone E/M services on the Medicare Telehealth Services List after that period on a Category 3 basis, because the codes describe services that can only be furnished using audio-only telecommunications technology, and outside of the circumstances of the PHE, they do not describe services that are a substitute for an in-person visit. While we acknowledge that audio-only technology can be used to furnish mental health telehealth services to patients in their homes under certain circumstances after the PHE ends, two-way, audio-video communications technology continues to be the appropriate standard that will apply for Medicare telehealth services after the PHE and the 151-day extension period. As we noted in the CY 2021 PFS final rule (85 FR 84535), we will assign these Telephone E/M visit codes (CPT codes 99441, 99442, and 99443) a ''bundled'' status after the end of the PHE and the 151-day extension period, and we will post the RUC-recommended RVUs for these codes in accordance with our usual practice.

(3) GI Tract Imaging and Continuous Glucose Monitoring

We received requests to add CPT codes describing GI Tract Imaging, CPT code 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) and Ambulatory Continuous Glucose Monitoring, CPT code 95251 (*Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report*), to the Medicare Telehealth Services List on a Category 3 basis. We believe these codes may describe services that are inherently non-face-to-face services, (the patient need not be present in order for the service to be furnished in its entirety), and therefore, they do not describe services that are a substitute for an in-person visit. As stated earlier, we believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. For this and other reasons, we are not proposing to add these services to the Medicare Telehealth Services List on a Category 3 basis; we do not believe these CPT codes describe services that are a substitute for an in-person visit, and we believe that services that are not inherently face-to-face services are not services that can be furnished as Medicare telehealth services. Even so, we are interested in information that would help us to understand whether these services would meet the criteria for inclusion on the Medicare Telehealth Services List either for the PHE, as Category 3 services, or permanently on a Category 1 or 2 basis, given our questions as to whether they are inherently non-face-to-face services, and therefore, may not fit within the scope of services that could be furnished as Medicare telehealth services. Therefore, we are also seeking comment on whether these services would involve an in-person service when furnished without the use of a telecommunications system.

(4) Neurostimulator Pulse Generator/Transmitter

We received requests to add codes describing the electronic analysis of an implanted neurostimulator pulse generator/transmitter to the Medicare Telehealth Services List. These included a request to add CPT codes 95976 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) permanently on a Category 1 basis, as well as a request to add CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s],*

interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming), 95983 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional*), and 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)*) to the Medicare Telehealth Services List on a temporary Category 3 basis.

The request to add CPT codes 95976 and 95977, which are codes that describe analysis of cranial nerve neurostimulation, indicated that the ability to fully furnish this service using two-way, audio-video communication technology was forthcoming, but is currently unavailable. Therefore, we are not proposing to add CPT codes 95976 and 95977 to the Medicare Telehealth Services List, because the full scope of service elements described by these codes cannot currently be furnished via two-way, audio-video communication technology. However, we will consider additional evidence regarding the ability to furnish these services as telehealth services, such as information indicating that current technology has evolved, as it becomes available for future rulemaking. We are also not proposing to add them on a Category 1 basis because they do not describe services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List.

With regard to CPT codes 95970, 95983, and 95984, which describe general brain nerve neurostimulation, we have some concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE, and Medicare claims data suggest that these services are being provided via telehealth. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. With that said, CPT codes 95970, 95983, and 95984 do meet the criteria for temporary inclusion on the Medicare Telehealth Services List on a Category 3 basis. Therefore, we are proposing to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis, while soliciting comment on our concerns regarding patient safety and whether these services are appropriate for inclusion on the Medicare Telehealth Services List outside the circumstances of the PHE.

(5) Emotional/Behavior Assessment, Psychological, or Neuropsychological Testing and Evaluation Services

We received requests to add a number of emotional/behavior assessment, psychological, or neuropsychological testing and evaluation services, described by CPT codes 97151 (*Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan*), 97152 (*Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes*), 97153 (*Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes*), 97154 (*Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes*), 97155 (*Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes*), 97156 (*Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes*), 97157 (*Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes*), 97158 (*Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes*), 0362T (*Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*), and 0373T (*Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*) to the Medicare Telehealth Services List permanently on a Category 2 basis. These services are currently on

the Medicare Telehealth Services List temporarily for the duration of the PHE. We believe that, for these services, there is likely to be clinical benefit when furnished via telehealth, and therefore, they meet the criteria for temporary inclusion on a Category 3 basis. We did not identify these services during our initial assessment of services that should be temporarily available on the Medicare Telehealth Services List on a Category 3 basis in the CY 2021 rulemaking; however, we are now proposing to include these services on the Medicare Telehealth Services List on a Category 3 basis, in light of information we received from the requestors describing the potential clinical benefit of these services when furnished via telehealth. However, we do have concerns regarding whether, outside the circumstances of the PHE, the full scope of service elements can occur in a manner that does not jeopardize quality of care, whether this patient population could be fully assessed via interactive audio-video technology, and whether these services could be conducted in a way that maintains the safety of the beneficiary. This patient population often includes patients with moderate to severe challenges in oral communication, and they may require close observation of their movements within all of their environmental cues, which include, for instance, smell, sound, and colors around the room. We are concerned that two-way, audio and video communications technology would not fully capture these behavioral nuances. We believe more time may be necessary to develop evidence that could support the decision to add these services to the Medicare Telehealth Services List permanently on a Category 1 or Category 2 basis. We are soliciting comment on our patient safety concerns.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

As discussed above, there are services that are included on the Medicare Telehealth Services List temporarily during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition to the list under the Category 1 or Category 2 criteria. In addition to the services discussed above that we are proposing for addition to the Medicare Telehealth Services List on a Category 3 basis in response to requests, we are also proposing to add a number of services to the list on a Category 3 basis that are currently included on the Medicare Telehealth Services List temporarily during the PHE. These services would be included on the Medicare Telehealth Services List through 2023 to allow us to evaluate data that may support their permanent addition to the list on a Category 1 or Category 2 basis.

The services we are proposing for inclusion to the Medicare Telehealth Services List on a Category 3 basis include CPT codes 90875 (*Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes*), 92012 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*), 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*), 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*), 94005 (*Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more*), 96105 (*Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, e.g., by Boston Diagnostic Aphasia Examination*) with interpretation and report, per hour), 96110 (*Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument*), 96112 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour*), 96113 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)*), 96127 (*Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument),* 96170 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)*), 97129 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes*), 97130 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)*), and 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*). Our analyses of these services indicate that there is some evidence of possible clinical benefit associated with these services when furnished via telehealth. We believe these services can safely be furnished via real-time, audio and visual interactive telecommunications under the circumstances of the PHE, but there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria.

Some audiology testing services are currently temporarily available on the Medicare Telehealth Services List for the duration of the PHE. These are CPT codes 92550 (*Tympanometry and reflex threshold measurements*), 92552 (*Pure tone audiometry (threshold); air only*), 92553 (*Pure tone audiometry (threshold); air and bone*), 92555 (*Speech audiometry threshold;*), 92556 (*Speech audiometry threshold; with speech recognition*), 92557 (*Comprehensive audiometry threshold*

evaluation and speech recognition (92553 and 92556 combined)), 92563 (*Tone decay test*), 92565 (*Stenger test, pure tone*), 92567 (*Tympanometry (impedance testing)*), 92568 (*Acoustic reflex testing, threshold*), 92570 (*Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing*), 92587 (*Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3–6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report*), 92588 (*Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report*), 92601 (*Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming*), 92625 (*Assessment of tinnitus (includes pitch, loudness matching, and masking)*), 92626 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour*), 92627 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)*). We have received information that, during the PHE, certain practitioners have developed the capacity to perform these services using remote technology including specialized equipment inside an audiometric soundproof booth. We believe that, in circumstances in which such equipment is available at the originating site, these services can be furnished in a way in which all of the elements of the services are met and that there is likely to be a clinical benefit when these services are furnished via telehealth. Therefore, we are proposing to add these services to the Medicare Telehealth Services List on a Category 3 basis, which would allow these services to be available via telehealth through the end of CY 2023. We are soliciting comments regarding how widespread the availability of this remote technology is, and whether interested parties believe these services can be furnished in a way that does not jeopardize patient safety or quality of care when these services are furnished remotely.

Additionally, as discussed in section II.F. of this proposed rule, we are proposing to create HCPCS codes GXXX1 (*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report GXXX1 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report GXXX1 for any time unit less than 15 minutes)*), GXXX2 (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report GXXX2 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0,). (Do not report GXXX2 for any time unit less than 15 minutes)*), and GXXX3 (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report GXXX3 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report GXXX3 for any time unit less than 15 minutes)*) to describe prolonged services associated with certain types of E/M services. These codes would be replacing existing codes that describe prolonged services, specifically inpatient prolonged services CPT codes 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient or observation Evaluation and Management service)*) and 99357 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*). These services are similar to services currently on the Medicare Telehealth Services List, such as CPT codes 99356 and 99357, which were added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2016 rule (80 FR 71060–71062), as well as O/O prolonged service HCPCS code G2212 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*), which was added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2021 rule (85 FR 84506). Similarly, we believe that these proposed HCPCS G codes would be sufficiently similar to psychiatric diagnostic procedures or O/O visits currently on the Medicare Telehealth Services List to qualify for inclusion on the list on a Category 1 basis. Therefore, we are proposing to add proposed HCPCS codes GXXX1, GXXX2, and GXXX3 to the Medicare Telehealth Services List on a Category 1 basis.

Table 8 lists the services that we are proposing for addition to the Medicare Telehealth Services List on a Category 3 basis. Table 9 lists the services we are proposing for permanent addition to the Medicare Telehealth Services List on a Category 1 basis.

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TABLE 8: Services Proposed for addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of CY 2023

HCPCS	Short Descriptor
90875	Psychophysiological therapy
90901	Biofeedback train any meth
92012	Eye exam estab pat
92014	Eye exam & tx estab pt 1/>vst
92507	Speech/hearing therapy
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
94005	Home vent mgmt supervision
95970	Alys npgt w/o prgrmg
95983	Alys brn npgt prgrmg 15 min
95984	Alys brn npgt prgrmg addl 15
96105	Assessment of aphasia
96110	Developmental screen w/score
96112	Devel tst phys/qhp 1st hr
96113	Devel tst phys/qhp ea addl
96127	Brief emotional/behav assmt
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97150	Group therapeutic procedures
97151	Bhv id assmt by phys/qhp
97152	Bhv id suprt assmt by 1 tech
97153	Adaptive behavior tx by tech
97154	Grp adapt bhv tx by tech
97155	Adapt behavior tx phys/qhp
97156	Fam adapt bhv tx gdn phy/qhp
97157	Mult fam adapt bhv tx gdn
97158	Grp adapt bhv tx by phy/qhp
97537	Community/work reintegration
97542	Wheelchair mngment training
97530	Therapeutic activities
97763	Orthc/prostc mgmt sbsq enc
98960	Self-mgmt educ & train 1 pt
98961	Self-mgmt educ/train 2-4 pt
98962	Self-mgmt educ/train 5-8 pt
99473	Self-meas bp pt educaj/train
0362T	Bhv id suprt assmt ea 15 min
0373T	Adapt bhv tx ea 15 min

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TABLE 9: Services Proposed for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS	Short Descriptor
GXXX1	Prolonged inpatient or observation services by physician or other QHP
GXXX2	Prolonged nursing facility services by physician or other QHP
GXXX3	Prolonged home or residence services by physician or other QHP

d. Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE

As we noted in the CY 2022 PFS final rule (86 FR 65054), at the conclusion of the PHE for COVID–19, the associated waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through our regular notice-and-comment rulemaking process, through which we established Medicare Telehealth Services List. Services that have been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of CY 2023. Under our current policy, all other services that were temporarily added to the Medicare Telehealth Services List on an interim basis during the PHE and have not been added to the Medicare Telehealth Services List on a Category 1, 2, or 3 basis will not remain on the list after the end of the PHE (85 FR 84506–84509). As explained in section II.D.1.e. of this proposed rule, Division P, Title III, Subsection A of the Consolidated Appropriations Act, 2022 (CAA, 2022), extends some of the flexibilities implemented during the PHE for COVID–19 for an additional 151 days after the end of the PHE, including Section 301(a) of Division P, Title III, Subtitle A of the CAA, 2022, which specifies that, for services on the Medicare Telehealth Services List as of the date of enactment (March 15, 2022) furnished during 151 days after the end of the PHE, the originating site for the telehealth service can be any site in the United States at which the beneficiary is located when the service is furnished, including the beneficiary's home. To give full effect to this provision, we believe it is necessary to continue to include the services on the Medicare Telehealth Services List through the 151-day period after the end of the PHE that were temporarily added to the list during the PHE but have not since been added on a Category 3 or other basis, and which are currently set to be removed from the list at the end of the PHE. As such, we are proposing to continue to include on the Medicare Telehealth Services List the services that are currently set to be removed from the list when the PHE ends (that is, those not currently added to the list on a Category 1, 2, or 3 basis) for an additional 151 days after the PHE ends. Table 10 lists those services that are temporarily available for the PHE, which we are proposing to retain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE. The services listed in Table 10 will no longer be available on the Medicare Telehealth Services List on the 152nd day after the end of the PHE. On the 152nd day after the end of the PHE, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, as aforementioned, and telehealth claims for these codes will be denied. We are proposing to align those services that had been planned to stop being available as Medicare telehealth at the end of the PHE with the 151-day extensions of flexibilities enacted in the CAA, 2022 in order to simplify the process of when flexibilities will end and to minimize possible errors.

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TABLE 10: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following End of the PHE

HCPCS	Short Descriptor
77427	Radiation tx management x5
92002	Eye exam new patient
92004	Eye exam new patient
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
93750	Interrogation vad in person
94002	Vent mgmt inpat init day
94003	Vent mgmt inpat subq day
94004	Vent mgmt nf per day
96125	Cognitive test by hc pro
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99324	Domicil/r-home visit new pat
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99441	Phone e/m phys/qhp 5-10 min
99442	Phone e/m phys/qhp 11-20 min
99443	Phone e/m phys/qhp 21-30 min
99468	Neonate crit care initial
99471	Ped critical care initial
99475	Ped crit care age 2-5 init
99477	Init day hosp neonate care

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e. Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022

As discussed in the CY 2021 PFS final rule (85 FR 84506), legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We used these authorities to establish several flexibilities to accommodate changes in the delivery of care during the PHE. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. At the end of the PHE for COVID–19, these waivers and interim policies will expire, and payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act.

Section 1834(m)(7) of the Act (as added by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018)), removes the geographic restrictions under section 1834(m)(4)(C)(i) of the Act and authorizes the patient's home as a permissible originating site, for telehealth services furnished for purposes of treatment of a substance use disorder (SUD) or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. Section 123(a) of Division CC of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020) amended section 1834(m)(7)(A) of the Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and for which the patient's home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID–19. Section 123(a) of the CAA, 2021 also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7), unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. For a full discussion of our implementation of section 123(a) of the CAA, 2021, refer to our CY 2022 PFS final rule (86 FR 64996).

In this proposed rule, we are proposing to implement provisions of section 1834(m) of the Act (including the amendments made by the CAA, 2021) and provisions of the CAA, 2022 that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE.

Sections 301, 302, 303, 304, and 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that are on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). Specifically, section 301(a) of the CAA, 2022 amended section 1834(m)(4)(C) of the Act to add a new clause (iii), which temporarily expands the scope of telehealth originating sites for those services to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID–19. Section 301(a) also amended section 1834(m)(7)(A) of the Act to apply the expanded scope of telehealth originating site policy to include any location in the United States in new clause (iii) of section 1834(m)(4)(C) of the Act during the 151-day period for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and to individuals with a SUD diagnosis for purposes of treatment of the SUD or a co-occurring mental health disorder for this 151-day post-PHE extension period. In addition to this provision, section 301(b) of the CAA, 2022 amended section 1834(m)(2)(B) of the Act to add a new clause (iii) that allows payment of an originating site facility fee to an originating site with respect to those telehealth services furnished during the 151-day period only if the originating site is one that meets the geographic requirements in section 1834(m)(4)(C)(i) of the Act, and is a setting included on the enumerated list of originating sites under section 1834(m)(4)(C)(ii) of the Act (other than the patient's home).

Section 302 of the CAA, 2022 amended section 1834(m)(4)(E) of the Act to temporarily expand the definition of eligible telehealth practitioners for the 151-day period beginning on the first day after the end of the PHE for COVID–19 to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists.

Section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to temporarily continue payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE using the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which, in accordance with section 1834(m)(8)(B) of the Act, is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

Section 304(a) of the CAA, 2022 amended section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on the 152nd day after the PHE ends. In addition, section 304(b) and (c) of the CAA, 2022 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we are proposing to revise the regulatory text at § 410.78(b)(3)(xiv) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19, to conform with the statute. See section II.B.3. of this proposed rule for our proposal to implement similar changes for RHC and FQHC mental health visits.

Finally, section 305 of the CAA, 2022 added a new paragraph (9) to section 1834(m) of the Act to require the Secretary to continue to provide for coverage and payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2022, date of enactment that are furnished via an audio-only telecommunications system during the 151-day period beginning on the first day after the end of the PHE for COVID–19. The new paragraph applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are designated to as eligible to be furnished via audio-only technology as of the date of enactment of the CAA, 2022 (that is, March 15, 2022). These are the services for which CMS waived the requirements of section 1834(m)(1) of the Act and the first sentence of § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, during the PHE. Under this waiver, CMS permitted the audio-only telephone E/M services and certain behavioral health counseling and educational services to be furnished via audio-only equipment during the PHE for COVID–19. CMS is proposing to continue to make payment for services included on the Medicare Telehealth Services List as of March 15, 2022 that are furnished via an audio-only telecommunications system for the 151-day period beginning on the first day after the end of the PHE. We read section 305 of the CAA, 2022 to require that we continue to make payment for services furnished via audio-only telecommunications systems (each described by a HCPCS code, including their successor codes) for the 151-day period after the end of the PHE. These services include certain behavioral health, counseling, and educational services. A list of the services that involve audio-only interaction but are included on the Medicare Telehealth Services List for the duration of the PHE is available at the CMS website, *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.*

Section 309 of Division P, Title III, Subtitle A of the CAA, 2022 authorizes the Secretary to implement the amendments described above made by sections 301 through 305 through program instruction or otherwise. Given that the end date of the PHE is not yet known and could occur before the rulemaking process for the CY 2023 PFS is complete, and that the changes made by these provisions are very specific and concise, we are providing notice that we intend to issue program instructions or other subregulatory guidance to effectuate the changes described above, other than the proposed revisions to § 410.78, in the near future. We believe this approach will serve to ensure a smooth transition after the end of the PHE for COVID–19.

f. Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID–19

Prior to CY 2017, Medicare telehealth services furnished via interactive audio and video telecommunications systems were reported using the GT modifier. In the CY 2017 PFS Final Rule, CMS finalized creation of a new Place of Service (POS) code for Medicare telehealth, POS ''02'' (81 FR 80199–80201). When a physician or practitioner submits a claim for their services, including claims for telehealth services, they include a place of service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate and the non-facility (or office) rate. The PFS non-facility rate is the single amount paid to a physician or other practitioner for services furnished in their office. The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care, like a hospital, where Medicare is making a separate payment to a facility entity in addition to the payment to the billing physician or practitioner. This separate payment, often referred to as a ''facility fee,'' reflects the facility's costs associated with the service (clinical staff, supplies, and equipment) and is paid in addition to what is paid to the professional under the PFS. POS ''02'' indicates payment at the facility payment rate.

As discussed in the March 31, 2020 IFC, (refer to 85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID–19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in person. This would allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for the COVID–19 pandemic, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which should be applied to claim lines that describe services furnished via telehealth and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth.

We further noted that we are maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for the COVID–19 pandemic.

We propose that Medicare telehealth services furnished on or before the 151st day after the end of the PHE, in alignment with the extensions of telehealth-related flexibilities in the CAA, 2022, will continue to be processed for payment as Medicare telehealth claims when accompanied with the modifier ''95''. We further propose that physicians and practitioners can continue to report the place of service code that would have been reported had the service been furnished in-person during the 151-day period after the end of the PHE, as finalized on an interim basis in the March 31 IFC (85 FR 19233). Medicare telehealth services performed with dates of service occurring on or after the 152nd day after the end of the PHE will revert to pre-PHE rules and will no longer require modifier ''95'' to be appended to the claim, but the appropriate place of service (POS) indicator will need to be included on the claim to be processed for payment as Medicare telehealth claims in order to properly identify the place where the service was furnished. For Medicare telehealth services furnished on or after the 152nd day after the end of the PHE, the POS indicators for Medicare telehealth will be:

- POS ''02''—which would be redefined, if finalized, as Telehealth Provided Other than in Patient's Home (*Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology.*); and

• POS ''10''—Telehealth Provided in Patient's Home (*Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.*).

We remind readers that we defined ''home'' in our CY 2022 PFS final rule (86 FR 65059) as: ''both in general and for this purpose, a beneficiary's home can include temporary lodging, such as hotels and homeless shelters. We clarified that for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished 'in the home of an individual' for purposes of section 1834(m)(4)(C)(ii)(X) of the Act.''

Once the flexibilities for the geographic restrictions and the site of service waivers for Medicare telehealth services expire (on the 152nd day after the end of the PHE, per the CAA, 2022), POS ''02'' will once again be required for all Medicare telehealth claims. The exceptions include claims for Medicare telehealth mental health services, clinical assessments for patients with ESRD that are receiving home dialysis, and Medicare telehealth mental health services that are co-occurring with substance use treatment that are furnished with the patient in their home (that is, the originating site is in a private residence and not a hospital or other facility setting), in which case POS ''10'' could be used by the billing practitioner. On or after the 152nd day after the PHE has expired, payment for Medicare telehealth services using either of the Medicare telehealth POS codes will be made at the PFS facility payment rate, in accordance with established policy outside the circumstances of the PHE. We propose to align those telehealth services described as taking place in the beneficiary's home, using POS ''10'' for Medicare telehealth, and those services not provided in a patient's home, using POS ''02'' for Medicare telehealth, to be made at the same facility payment amount. We believe that the facility payment amount best reflects the practice expenses, both direct and indirect, involved in furnishing services via telehealth (please see section II.B. of this proposed rule for further discussion regarding practice expense).

We further propose that, beginning January 1, 2023, a physician or other qualified health care practitioner billing for telehealth services furnished using audio-only communications technology shall append CPT modifier ''93'' (*Synchronous Telemedicine Service Rendered Via Telephone or Other Real-Time Interactive Audio-Only Telecommunications System: Synchronous telemedicine service is defined as a real-time interaction between a physician or other qualified health care professional and a patient who is located away at a distant site from the physician or other qualified health care professional. The totality of the communication of information exchanged between the physician or other qualified health care professional and the patient during the course of the synchronous telemedicine service must be of an amount and nature that is sufficient to meet the key components and/or requirements of the same service when rendered via a face-to-face interaction*) to Medicare telehealth claims (for those services for which the use of audio-only technology is permitted under § 410.78(a)(3)), to identify them as having been furnished using audio-only technology. We note that CMS has instructed RHCs, FQHCs, and OTPs to append Medicare modifier ''FQ'' (*Medicare telehealth service was furnished using audio-only communication technology*) for allowable audio-only services furnished in those settings; however, consistent with our proposal for audio-only services furnished under the PFS, we are also proposing to require RHCs, FQHCs, and OTPs to use modifier 93 when billing for eligible mental health services furnished via audio-only telecommunications technology. We believe that using modifier ''93'', which is a CPT modifier, will simplify billing, as this modifier is used by payers outside of Medicare. Currently, these modifiers can only be applied to Medicare telehealth mental health services and those telehealth services for the treatment of a SUD or a co-occurring mental health disorder when the originating site is the beneficiary's home.

Supervising practitioners continue to be required to append the ''FR'' modifier on any applicable telehealth claim when required to be present through an interactive real-time, audio and video telecommunications link, as reflected in each service's requirement.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner.

For professional services furnished incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), statutory requirements for immediate availability and accessibility of a physician are met if the physician meets the requirements for direct supervision for physician office services at § 410.26 and for hospital outpatient services at § 410.27. Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially

relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners can only bill Medicare for telehealth services under Medicare telehealth waivers that are effective only during the PHE for COVID–19 (per the emergency waiver authority established in section 1135(b)(8) of the Act), and for 151 days after the final day of the PHE for COVID–19, as mandated by the CAA, 2022. We note that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth service. Outside of the PHE and the 151-day period after the PHE ends, such clinicians include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We remind readers that after December 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their own professional services would no longer apply, so telehealth services can no longer be performed by clinical staff incident to a physician's professional service.

While we are not proposing to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, as with last year's rulemaking (86 FR 39149–50), we continue to seek information on whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology should potentially be made permanent. We also seek comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time, audio/video technology for only a subset of services, as we recognize that it may be inappropriate to allow direct supervision without physical presence for some services due to potential concerns over patient safety. As discussed in last year's final rule (86 FR 65063), and based on gaps in the currently available evidence, we are in need of more information as we consider whether to make permanent a temporary exception to our direct supervision policy.

3. Telehealth Originating Site Facility Fee Update

Section 1834(m)(2)(B) of the Act established the initial Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00, and specifies that for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI increase for CY 2023 is 3.7 percent and is based on the most current forecast of the percentage increase of the 2006-based MEI for the second quarter of 2022 (4.1 percent), and the most recent estimate of the historical productivity adjustment for calendar year 2021 (0.4 percent).

Therefore, for CY 2023, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $28.61. The final Medicare telehealth originating site facility fee will be revised for the final rule based on the historical data through the second quarter 2022 and the most recently available total factor productivity data. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period are shown in Table 11.

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TABLE 11: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023*	3.7	$ 28.61

* Proposed

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E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we solicit public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we consider and responded to public comments received on the interim final values, and typically make any appropriate adjustments and finalize those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature,

Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. We also include a summary of interested party reactions to our approach when available. We note that many commenters and interested parties have expressed concerns over the years with our reviews of and updates to work RVUs based on changes in the best available information regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we use to update the RVUs is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for

a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the ''old time'' values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies to adjust for reductions in time, suggesting that our adjustments to the RUC-recommended work RVUs are inappropriate. Other interested parties have expressed general concerns with our refinements to RUC-recommended values. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding our approach to RUC-recommended work times and RVUs. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 14 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of PE RVUs, we address certain proposed refinements that would be common across codes. We address refinements to particular codes in the portions of section II.B. that focus on particular codes. We note that for each refinement, we indicate the potential impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that many of the refinements listed in Table 13 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the proposed direct PE inputs for CY 2023 are displayed in the CY 2023 direct PE input files, available on the CMS website under the downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the proposed CY 2023 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined

or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of PE RVUs, for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2023, we received invoices for several new supply and equipment items. Tables 15 and 16 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 15 and 16 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate

proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2023 are available on the CMS website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if— (i) The technical component (TC) (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for hospital outpatient (HOPD) services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by the section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography. For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2023, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined above for purposes of this cap. Beginning for CY 2023, we propose to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0493T (*Contact near-infrared spectroscopy studies of lower extremity wounds (e.g., for oxyhemoglobin measurement)*), 0640T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound*), 0641T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound*), 0642T (*Noncontact near-infrared spectroscopy studies of flap or wound (e.g., for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound*), 0651T (*Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report*), 0658T (*Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score*), 0689T (*Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure)*), 0690T (*Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)*), 0694T (*3-dimensional volumetric imaging and reconstruction of breast or axillary lymph node tissue, each excised specimen, 3-dimensional automatic specimen reorientation, interpretation and report, real-time intraoperative*), 0700T (*Molecular fluorescent imaging of suspicious nevus; first lesion*), 0701T (*Molecular fluorescent imaging of suspicious nevus; each additional lesion (List separately in addition to code for primary procedure)*), and 76XX0 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*).

4. Valuation of Specific Codes for CY 2023

(1) Anterior Abdominal Hernia Repair (CPT Codes 157X1, 49X01, 49X02, 49X03, 49X04, 49X05, 49X06, 49X07, 49X08, 49X09, 49X10, 49X11, 49X12, 49X13, 49X14, and 49X15)

In April 2021, the RUC reviewed an existing code that describes hernia repair, CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*). CPT code 49565 was identified as being performed less than 50 percent of the time in the inpatient setting and being primarily performed in the outpatient setting. Interested parties requested referral to CPT to update the code's descriptor. In response to the disparate site of service and request to update the code's descriptor, CPT created new codes with 000-day global periods to describe this type of service. The codes within this family are differentiated by 3 characteristics: whether the hernia is initial or recurrent, whether it is reducible or strangulated, and the total length of the hernia. CPT also created two new codes that describe parastomal

hernia repair and an add-on code for removal of mesh.

The RUC recommendations differentiate the post-operative periods for the codes within this family by whether there is a same-day discharge, overnight stay with a visit on the same date, or whether the patient is admitted to the hospital. We disagree with many of the RUC-recommended work RVUs for the codes within this family that have a post-operative overnight stay built into their valuation. More specifically, we disagree with the RUC-recommended work RVUs for such codes because the RUC did not completely apply the 23-hour policy calculation (finalized in the CY 2011 PFS final rule (75 FR 73226)) in formulating its recommendations. Additionally, we disagree with the RUC-recommended work RVUs for the CPT codes in this family for which the RUC considered the patient to be admitted during the post-operative period because the RUC did not apply the 23-hour policy when formulating its recommendations.

As we noted in the CY 2011 PFS final rule (75 FR 73226), the work RVUs for services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment. Because such services are typically furnished in the outpatient setting, they should not be valued to include inpatient post-operative E/M visits. The level of discharge day management services included in the valuation of such services should similarly not reflect an inpatient discharge and should therefore be reduced. And finally, as discussed in CY 2011 rulemaking, the intraservice time from the inpatient level E/M postoperative visit should be reallocated to the immediate postservice time of the service. The 23-hour policy calculation, when fully applied to the calculation of a work RVU, is used to reduce the value of discharge day management services, remove the inpatient E/M visits, and reallocate the intraservice time to the immediate post-service period. See the CY 2011 PFS final rule (75 FR 73226) for additional in-depth explanation of the 23-hour policy.

For the codes with an overnight stay and an E/M visit on the same date built into their valuation, we believe the RUC only partially applied the 23-hour policy when it applied the policy to the immediate post service times, but not to the calculation of the work RVUs. Instead, we believe the 23-hour policy should be fully applied to the codes in this family that describe outpatient services for which there is an overnight stay during the post-operative period, regardless of the number of nights that a patient stays in the hospital. The services to which the 23-hour policy is usually applied would typically involve a patient stay in a hospital for less than 24 hours, which often means the patient may stay overnight in the hospital. On occasion, the patient may stay in the hospital longer than a single night; however, in both cases (one night or more than one night), the patient is considered to be a hospital outpatient, not an inpatient, for Medicare purposes. In short, we do not believe that the work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies.

The RUC recommended a work RVU of 8.0 for CPT code 157X1 (*Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma*). CPT code 157X1 was surveyed with having one subsequent hospital visit, CPT code 99232 (*subsequent hospital care/day 25 minutes*) and 25 minutes of immediate post service time. For purposes of calculating the recommended work RVU of 8.0, the RUC considered CPT code 157X1 to describe an inpatient service, while we consider CPT code 157X1 to describe an outpatient service for purposes of Medicare billing. As noted above, we do not believe that work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies. Therefore, the valuation for this code should not include inpatient work in the post-operative period. See the CY 2022 PFS final rule (86 FR 65090) for further discussion on the 23-hour policy as it relates to outpatient billing. We believe the 23-hour policy should be fully applied to CPT code 157X1, and we disagree with the RUC-recommended work RVU of 8.0.

In accordance with the 23-hour policy valuation methodology we established in the CY 2011 PFS final rule, we are instead proposing a work RVU of 7.05 for CPT code 157X1 and a reallocation of the time associated with the intra-service portion of the inpatient hospital visit to the immediate postservice time of CPT code 157X1.

The steps for the 23-hour policy calculation are as follows:

- Step (1): CPT code 157X1 does not have a hospital discharge day management service; therefore, we will skip this step *.
- Step (2): 8.0 − 1.39 ** = 6.61.
- Step (3): 6.61 + (20 minutes × 0.0224) *** = 7.05 RVUs.

* Value associated with ½ hospital discharge day management service

** Value associated with an inpatient hospital visit, CPT code 99232.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

The following CPT codes have a post-operative period that is considered an overnight stay with a visit on the same date: CPT codes 49X02 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), 49X03 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, reducible*), 49X04 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated*), 49X05 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, reducible*), 49X08 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), and 49X09 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, reducible*). The RUC recommended a work RVU of 9.0 for CPT code 49X02, 10.80 for CPT code 49X03, 14.0 for CPT code 49X04, 14.88 for CPT code 49X05, 10.79 for CPT code 49X08, and 12.0 for CPT code 49X09. CPT codes 49X02, 49X03, 49X08, and 49X09 were surveyed with

one subsequent inpatient hospital visit at a level of CPT code 99231 (*subsequent hospital care/day 15 minutes*). The RUC applied the 10 minutes of intraservice time from CPT code 99231 to the immediate postservice time of these codes, resulting in a total immediate postservice time of 30 minutes for these codes. CPT codes 49X04 and 49X05 were surveyed with a subsequent inpatient hospital visit at a level of CPT code 99232. The RUC applied the 20 minutes of intraservice time from CPT code 99232 to the immediate postservice time of both codes, resulting in a total immediate postservice time of 40 minutes.

Much like our concerns regarding the RUC-recommended work RVU for CPT code 157X1, we do not believe that the RUC fully applied the 23-hour policy calculation when calculating the work RVUs for these codes and we disagree with the RUC-recommended RVUs. While the RUC removed the 99231 and 99232 inpatient visits included in the post-operative period for these codes, the RUC did not subtract the values of these visits from the work RVUs before making their work RVU recommendations. In the CY 2011 PFS final rule (75 FR 73226), we stated that we do not believe that the post-procedure hospital visits for outpatient services should be at the inpatient level since the typical case is an outpatient who would be ready to be discharged from the hospital in 23 hours or less. However, we agree with the RUC that the intra-service time of the inpatient hospital visit may be included in the valuation for 23-hour stay codes. Therefore, we believe that step 2 of the 23-hour hour policy calculation, which involves deducting the RVUs of the inpatient hospital visits from the starting work RVU value and subsequently reallocating the time associated with the intra-service portion of the inpatient hospital visits to the immediate postservice time of the 23-hour stay code, should be fully applied when calculating the work RVUs for CPT codes 49X02, 49X03, 49X04, 49X05, 49X08, and 49X09.

Using the 23-hour policy calculation described above and in the CY 2011 PFS final rule, we are proposing work RVUs of 8.46 for CPT code 49X02, 10.26 for CPT code 49X03, 13.46 for CPT code 49X04, 13.94 for CPT code 49X05, 10.25 for CPT code 49X08, and 11.46 for CPT code 49X09.

The following CPT codes have a post-operative period that the RUC considers to be admitted to a hospital: CPT code 49X06 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*), 49X10 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated*), 49X11 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, reducible*), 49X12 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*), 49X13 (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible*), and 49X14 (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated*). The RUC recommended a work RVU of 18.67 for CPT code 49X06, 15.55 RVUs for CPT code 49X10, 16.03 RVUs for CPT code 49X11, 22.67 RVUs for CPT code 49X12, 13.70 RVUs for CPT code 49X13, and 17.06 RVUs for CPT code 49X14. CPT codes 49X06 and 49X12 were surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99233 (*subsequent hospital care/day 35 minutes*). The RUC recommendations include an immediate postservice time of 25 minutes for CPT code 49X06 and 30 minutes for CPT code 49X12. CPT codes 49X10, 49X11, and 49X14 were surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99232. The RUC recommendations include an immediate postservice time of 25 minutes for 49X10, 28 minutes for CPT code 49X11, and 25 minutes for CPT code 49X14. CPT code 49X13 was surveyed and recommended with one subsequent inpatient hospital visit at a level of CPT code 99231 and an immediate postservice time of 25 minutes.

For purposes of calculating the recommended work RVUs, the RUC considered these CPT codes to describe an admitted inpatient service, while we consider the CPT codes to describe outpatient services for purposes of billing. Therefore, we believe that inpatient work in the post-operative period should not be included in the valuation. We believe the 23-hour policy should be applied to these codes. Using the 23-hour policy calculation described above and in the CY 2011 PFS final rule, we are proposing a work RVU of 18.67 for CPT code 49X06, 15.55 RVUs for CPT code 49X10, 16.03 RVUs for CPT code 49X11, 22.67 RVUs for CPT code 49X12, 13.70 RVUs for CPT code 49X13, and 17.06 RVUs for CPT code 49X14. We are also proposing revised immediate postservice times for the reallocation of the time associated with the intraservice portion of the inpatient hospital visit. We are proposing immediate post service times of 40 minutes for CPT code 49X06, 35 minutes for CPT code 49X10, 38 minutes for CPT code 49X11, 45 minutes for CPT code 49X12, 30 minutes for CPT code 49X13, and 35 minutes for CPT code 49X14.

The following CPT codes have a post-operative period that the RUC considers to be a same day discharge: CPT code 49X01 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian*), *any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, reducible*) and 49X07 (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed, total length of defect(s); less than 3 cm, reducible*). The RUC-recommended a work RVU of 6.27 for CPT code 49X01 and 7.75 for CPT code 49X07. We disagree with the RUC-recommended RVU for CPT code 49X01 because it falls above the median value for codes with similar times. We are proposing a work RVU of 5.96 RVUs based on the intraservice time ratio, which is the ratio of 90 minutes of intraservice time of a current hernia repair code—CPT code 49560 (*Repair initial incisional or ventral hernia; reducible*) and the 45 minutes of intraservice time for CPT code 49X01. The proposed work RVU of 5.96 is also supported by reference CPT code 93453 (*Combined right and left heart catheterization including*

intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed). CPT code 93453 has a work RVU of 5.99, the same intraservice time as CPT code 49X01(45 minutes), and a slightly higher total time of 113 minutes.

For CPT code 49X07, we disagree with the RUC-recommended work RVU of 7.75, as it is above the median range compared to codes with similar times. We are proposing a work RVU of 7.42 RVUs for CPT code 49X07 based off of the intraservice time ratio of 100 minutes of intraservice time for a current hernia repair code—CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*), compared to the 60 minutes of intraservice time for CPT code 49X07. The proposed work RVU of 7.42 is also supported by reference CPT code 52353 (*Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)*). CPT code 52353 has a work RVU of 7.50 with the same intraservice time of 60 minutes and a very similar total time of 133 minutes.

CPT code 49X15 (*Removal of total or near-total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic)*) is an add-on code. The RUC recommended a work RVU of 5.0 for CPT code 49X15. The RUC recommendation is higher than the work RVUs for many other CPT add-on codes with similar times. We are proposing a work RVU of 2.61 RVUs for CPT code 49X15, based on the reverse building block methodology. The proposed work RVU of 2.61 is also supported by reference CPT code 15774 (*Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 2.50 and the same total time of 45 minutes.

We reviewed the RUC-recommended direct PE inputs for all of the codes within this family. We disagree with the RUC's recommendations of 66 total minutes of clinical staff time for CPT codes 49X01 and 49X07, 60 total minutes of clinical staff time for CPT codes 49X02, 49X03, 49X04, 49X05, 49X06, 49X08, 49X09, 49X10, 49X11, 49X12, 49X13, and 49X14, and 20 total minutes of clinical staff time for CPT code 157X1. We note that the RUC recommended 090-day pre-service times for all of these codes despite surveying all of the services as 000-day services. In the CY 2022 PFS final rule (86 FR 65090), we stated we continue to believe that setting and maintaining clinical labor time and valuation standards provides greater consistency among codes that share clinical labor tasks and could improve relativity of values among codes. Therefore, we believe that the standard clinical labor packages that are in accordance with the surveyed global period continue to be the most appropriate for purposes of clinical labor valuation.

The RUC recommendations for CPT codes 49X01 and 49X07, and CPT codes 49X02, 49X03, 49X04, 49X05, 49X06, 49X08, 49X09, 49X10, 49X11, 49X12, 49X13, and 49X14, include the standard for 090-day preservice times for clinical labor activities, which is 60 minutes. For 49X01 and 49X07 in particular, the RUC also recommended an additional 6 minutes in the post service period to conduct patient communications. We disagree with the RUC-recommended 090-day times as these CPT codes were surveyed by the RUC as 000-day services and should have times consistent with 000-day services. Therefore, we are proposing the standard clinical labor times for a 000-day extensive package for a total pre-service clinical staff time of 30 minutes for CPT codes 49X01 through 49X14 with an additional standard 3 minutes of post-service patient communications for 49X01 and 49X07. CPT code 49X15 is an add-on code and does not have RUC-recommended direct PE inputs.

For CPT code 157X1, the RUC recommendation is 20 minutes of clinical staff activities, which is standard for an emergent procedure package. We do not agree that the service described by CPT code 157X1 should be considered an emergent procedure. Therefore, we are proposing the minimal clinical staff package minus pre-service education for CPT code 157X1, for a total of 12 clinical staff time minutes.

(2) Removal of Sutures or Staples (CPT Codes 15851, 158X1, and 158X2)

In October 2021, the CPT Editorial Panel approved the deletion of CPT code 15850 and revised CPT code 15851 (*Removal of sutures or staples requiring anesthesia (ie, general anesthesia, moderate sedation)*), and created two new related CPT add-on codes, 158X1 and 158X2, to describe *Removal of sutures or staples requiring anesthesia (i.e., general anesthesia, moderate sedation).* The RUC reviewed the three codes: 15851, 158X1 and 158X2 at the January 2022 RUC meeting.

After reviewing CPT code 15851, we are proposing the RUC-recommended work RVU of 1.10. CPT code 158X1 (*Removal of sutures OR staples not requiring anesthesia (List separately in addition to E/M code)*), and 1581X2 (*Removal of sutures OR staples not requiring anesthesia (List separately in addition to E/M code),* are valued by the RUC as PE-only codes. The RUC did not recommend any work inputs for these two add-on codes and we are not proposing any work RVU refinements.

We are also proposing the RUC-recommended direct PE inputs for CPT codes 15851, 158X1, and 158X2 without refinement.

(3) Arthrodesis Decompression (CPT Codes 22630, 22632, 22633, 22634, 63052, and 63053)

In October 2020, the CPT Editorial Panel approved the revision of four codes describing arthrodesis and the addition of two new add-on codes, CPT codes 63052 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)*) and 63053 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)*), to report laminectomy, facetectomy, or foraminotomy during posterior interbody arthrodesis, lumbar to more appropriately identify the decompression that may be separately reported. In January 2021, the RUC reviewed the survey results for the two new codes and expressed concern that the four base codes had not been surveyed along with the two new add-on codes. The RUC recommended that the entire family be resurveyed and presented for review at its April 2021 meeting. The RUC suggested that until new values could be established, interim values be established for CPT codes 63052 and 63053, which CMS revised for CY 2022 based on the survey data and RUC review available to us at the time of the development of the CY 2022 PFS proposed rule. We have noted in similar circumstances, such as the minimally invasive glaucoma surgery (MIGS) procedures with cataract surgery discussed in the CY 2022 PFS final rule (86 FR 65097), that it is best for entire

code families to be surveyed at the same time. We also noted that we finalized a policy in the CY 2015 PFS final rule (79 FR 67602 through 67609) to make all changes in the work and MP RVUs and the direct PE inputs for new, revised, and potentially misvalued services under the PFS by proposing and then finalizing such changes through notice and comment rulemaking, as opposed to initially finalizing changes on an interim final basis.

For CPT codes 22630 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar*), 22633 (*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar*), 22634 (*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment (List separately in addition to code for primary procedure)*), 63052, and 63053, we disagree with the RUC-recommended work RVUs of 22.09, 26.80, 7.96, 5.70, and 5.00, respectively, because these values do not account for the surveyed changes in time, and we are proposing a work RVU of 20.42 for CPT code 22630, a work RVU of 24.83 for CPT code 22633, a work RVU of 7.30 for CPT code 22634, the current work RVU of 4.25 for CPT code 63052 and a work RVU of 3.78 for CPT code 63053. For CPT code 22632 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)*), we agree with the RUC-recommended maintenance of the current work RVU of 5.22, as there were no surveyed changes in time.

We are proposing a work RVU of 20.42 for CPT code 22630 based on the reverse building block methodology to account for the surveyed 8-minute decrease in total time, 10-minute decrease in pre-service time, 30-minute decrease in intraservice time, and 2-minute decrease in immediate post-service time. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would be inappropriate to maintain the current work RVU given the significant decrease in intraservice time without adequate justification of increased intensity. There are currently three CPT code 99231 (*Subsequent hospital care/day 15 minutes*) and four CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter.*) visits bundled in CPT code 22630's 090-day global period and valuation. The RUC recommended that the post-operative period for CPT code 22630 change to include two CPT code 99232 (*subsequent hospital care/day 25 minutes*), one CPT code 99231, one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 visits. The currently bundled post-operative visits total to 6.16 work RVUs, whereas the RUC-recommended changes to the post-operative visits total 6.98 work RVUs, resulting in a 0.82 work RVU increase (if no other changes occurred to CPT code 22630). The proposed work RVU of 20.42 for CPT code 22630 maintains the same IWPUT of 0.067 and maintains the 0.82 work RVU difference between the current and RUC-recommended post-operative period. We believe this proposed work RVU is more accurate than the RUC-recommended work RVU because there was no obvious or explicitly stated rationale in the RUC's recommendations for the change in intensity of intraservice time, and there was a 30-minute decrease in intraservice time for CPT code 22630. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would be inappropriate to propose the RUC-recommended work RVU for CPT code 22630.

Similarly, we are proposing a work RVU of 24.83 for CPT code 22633, based on the reverse building block methodology, to account for the surveyed 56-minute decrease in total time, 20-minute decrease in intraservice time, and 33-minute decrease in post-operative time. The reverse building block methodology accounts for the time and intensity of post-operative work through long-established and agreed-upon times and intensities for bundled post-operative visits, and accurately adjusts for the changes occurring in the post-operative period. There is currently one post-operative CPT code 99232, two CPT code 99233 (*Subsequent hospital care/day 35 minutes*), and three CPT code 99213 visits bundled in CPT code 22633's valuation. The RUC recommended that the post-operative period for CPT code 22633 change to include two CPT code 99232, one CPT code 99231, one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 visits. The currently bundled post-operative visits total to 8.30 work RVUs, whereas the RUC-recommended changes to the post-operative visits total 6.98 work RVUs, resulting in a 1.32 work RVU decrease (if no other changes occurred to CPT code 22633). Using the reverse building block methodology, the proposed work RVU of 24.83 maintains the same IWPUT of 0.080 and the 1.32 work RVU difference between the current and RUC-recommended post-operative period. We believe this proposed work RVU is more accurate than the RUC-recommended work RVU because there was no obvious or explicitly stated rationale in the RUC's recommendations for the change in intensity of intraservice time, and there was a 20-minute decrease in intraservice time for CPT code 22633. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, it would be inappropriate to propose the RUC-recommended work RVU decrease of 0.95, which is only about three-quarters of the established decrease in work RVU of 1.32 and intensity from the changes in the post-operative period alone. We also considered the apparent decrease in intraservice time and the lack of an adequate justification for increased intensity to arrive at our proposed work RVU of 24.83 for CPT code 22633.

We are proposing a work RVU of 7.30 for CPT code 22634 based on a comparison to its base code, CPT code 22633. We used the proposed work RVU of 24.83 for the parent CPT code (22633) as the numerator and the current work

RVU for CPT code 22633 of 27.75 as the denominator, and multiplied that fraction by the current work RVU of 8.16 for CPT code 22634 to arrive at a proportionate proposed work RVU of 7.30 for CPT code 22634 ((24.83/27.75) * 8.16) = 7.30). The proposed work RVU accounts for the decrease in intraservice time and is well bracketed by CPT code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*), valued at 7.00 work RVUs with an intraservice time of 60 minutes, and CPT code 34833 (*Open iliac artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*), valued at 8.16 work RVUs with an intraservice time of 72 minutes.

CPT codes 63052 and 63053 were new add-on codes to report decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace for CY 2022. The proposed work RVU for CPT code 63052 would maintain the current work RVU, despite a surveyed change in time. In the CY 2022 PFS final rule, we finalized a work RVU of 4.25 for CPT code 63052 for CY 2022 based on a crosswalk to CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*), which has a work RVU of 4.25 and an intraservice time of 45 minutes. Despite a surveyed 5-minute intraservice time increase for CPT code 63052, we believe the crosswalk to CPT code 22853 is still valid, given that only 3 months passed between the two surveys, as it now has the same intraservice time as CPT code 63052, is a spinal procedure, and is an add-on code to the same base codes as CPT code 63052. Commenters on the CY 2022 PFS proposed rule supported the bracket of key reference service CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) and MPC CPT code 34812 (*Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)*), and therefore, we noted that the final work RVU of 4.25 for CY 2022 was supported by the commenters (86 FR 65092). CPT code 22552 has a work RVU of 6.50 and an intraservice time of 45 minutes, and commenters noted that CPT code 22552 has a higher intensity as anticipated for a surgical procedure and in comparison with a lumbar procedure. CPT code 34812 has a work RVU of 4.13 and 40 minutes of intraservice time, and commenters noted that this code involves open femoral artery exposure by groin incision and closure of the wound, typically for separately reported delivery of an endovascular prosthesis for an asymptomatic infrarenal abdominal aortic aneurysm. In comparison, exposure and closure for CPT code 63052 are performed as part of the primary arthrodesis code and the intraservice time includes higher intensity bony and soft tissue resection, and therefore, although both codes require the same time, the physician work and intensity of CPT code 63052 is greater than CPT code 34812.

In the CY 2022 PFS final rule, we finalized a work RVU of 3.19 for CPT code 63053 for CY 2022 based on an intraservice time ratio between CPT codes 63052 and 63053 ((30 minutes/40 minutes) * 4.25 = 3.19). We believe this intraservice time ratio between the two CPT codes is still valid, given that only 3 months passed between the two surveys, and therefore, we are proposing a work RVU of 3.78 based on the surveyed time changes for CPT codes 63052 and 63053 ((40 minutes/45 minutes) * 4.25 = 3.78) in order to maintain consistency with previous analysis of time and intensity of these two add-on codes. Due to the lack of an obvious or explicitly stated rationale in the RUC's April recommendations for the change in intensity between the January 2021 and April 2021 surveys, we relied on the changes in surveyed time to calculate the proposed work RVUs for CPT codes 63052 and 63053.

We are proposing the RUC-recommended PE inputs for CPT codes 22630 and 22633.

(4) Total Disc Arthroplasty (CPT Codes 22857 and 228XX)

In September 2021, the CPT Editorial Panel created CPT Category I code 228XX to describe *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)* and replace CPT Category III code 0163T (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)*), which prompted CPT codes 228XX and 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar*) to be surveyed for the January 2022 RUC meeting. At the January 2022 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for both CPT codes 22857 and 228XX were erroneous and that the codes should be resurveyed for the April 2022 RUC meeting. Therefore, we are proposing to maintain the RUC-recommended work RVU of 27.13 for CPT code 22857 and contractor pricing for CPT code 228XX for CY 2023. We will revisit the valuations of CPT codes 22857 and 228XX in future rulemaking when we have received the April 2022 RUC recommendations, based on our annual review process discussed in the Background section of this proposed rule.

(5) Insertion of Spinal Stability Distractive Device (CPT Codes 22869 and 22870)

For CPT codes 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*) and 22870 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)*), we are proposing to maintain the current work RVUs of 7.03 and 2.34, respectively. We are proposing the RUC-recommended direct PE inputs for CPT code 22869 without refinement.

(6) Knee Arthroplasty (CPT Codes 27446 and 27447)

CPT codes 27446 (*Arthroplasty, knee, condyle and plateau; medial OR lateral compartment*) and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) were reviewed by the RUC in April 2021. We previously reviewed CPT code 27447 in the CY

2021 PFS final rule; (see 85 FR 84609 and 84610 for our previous discussion). The RUC proposed a revised survey instrument to ask about additional pre-operative time and resources spent on pre-optimization patient work. The RUC agreed that the pre-service planning activities are being performed routinely for the typical patient but the inclusion of this work is not reflected in the 090-day global period structure. The RUC indicated that separate planning codes may be developed, or current codes such as the prolonged service codes may be reported for these activities.

We are proposing the RUC-recommended work RVU of 17.13 for CPT code 27446. The survey 25th percentile actually showed an increase in work RVU even though there was a decrease in total time. One post facility visit, CPT code 99232 (*Subsequent hospital care/day 25 minutes*), was removed and replaced with CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*) a post-operative visit in the office. Given a decrease in the total time spent and a lower level post-operative visit, it is reasonable that the work RVU went down. There was no change in the global period.

For CPT code 27447, the RUC reaffirmed the same valuation that it recommended for the CY 2021 PFS rulemaking cycle. Since we did not receive any new information regarding this code, we are not proposing to change our previously finalized values (see 85 FR 84609 and 84610 for our previous discussion of this code in the CY 2021 PFS final rule). We are proposing to maintain a work RVU of 19.60 for CPT code 27447, the value that we previously finalized through rulemaking. We are proposing the RUC-recommended direct PE inputs for CPT code 27446 and we are proposing to maintain the direct PE inputs for CPT code 27447.

(7) Endovascular Pulmonary Arterial Revascularization (CPT Codes 338X3, 338X4, 338X5, 338X6, and 338X7)

At the February 2021 meeting of the CPT Editorial Panel, CPT approved a new family of Category I CPT codes to describe percutaneous endovascular repair of pulmonary artery stenosis (PAS) by stent replacement. CPT codes 338X3 through 338X7 were surveyed by the RUC at the October 2021 RUC meeting.

We disagree with the RUC-recommended work RVU of 14.0 for CPT code 338X3 (*Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, unilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We are proposing the survey 25th percentile work RVU of 11.03 for CPT code 338X3. A work RVU of 11.03 is supported by a bracket of reference CPT codes, including CPT code 61650 and CPT code 61640. CPT code 61650 (*Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory*) has a work RVU of 10.0 and the same intraservice time of 90 minutes and the same total time of 206 minutes. CPT code 61640 (*Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel*) has a work RVU of 12.32 and an intraservice time of 90 minutes and a higher total time of 233 minutes.

There are no direct PE inputs for CPT Code 338X3.

We disagree with the RUC-recommended work RVU of 18.0 for CPT code 338X4 (*Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, bilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We are proposing the survey 25th percentile work RVU of 14.50. A work RVU of 14.50 is supported by a reference CPT code—CPT code 11005. CPT code 11005 (*Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; abdominal wall, with or without fascial closure*) has a work RVU of 14.24 and the same intraservice time of 120 minutes and nearly the same total time of 235 minutes.

There are no direct PE inputs for CPT Code 338X4.

We disagree with the RUC-recommended work RVU of 17.33 for CPT code 338X5 (*Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, unilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We are proposing the survey 25th percentile work RVU of 14.0. A work RVU of 14.0 is supported by a reference CPT code—CPT code 61640. CPT code 61640 (*Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel*) has a work RVU of 12.32 and the same intraservice time of 90 minutes and a higher total time of 233 minutes.

There are no direct PE inputs for CPT Code 338X5.

We disagree with the RUC-recommended work RVU 20.0 for CPT code 338X6 (*percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, bilateral*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 338X4 and 338X6 is equivalent to the RUC-recommended interval of 2.0 RVUs. Therefore, we are proposing a work RVU of 16.50 for CPT code 338X6, based on the recommended interval of 2.0 additional RVUs above our proposed work RVU of 14.50 for CPT code 338X4. A work RVU of 16.50 is also supported by a reference code—CPT code 11005. CPT code 11005 (*Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; abdominal wall, with or without fascial closure*) has a work RVU of 14.24 and the same intraservice time of 120 minutes and a higher total time of 265 minutes.

There are no direct PE inputs for CPT Code 338X6.

We disagree with the RUC-recommended RVU of 7.27 for CPT code 338X7 (*Percutaneous pulmonary artery revascularization by stent placement, each additional vessel or separate lesion, normal or abnormal connections (list separately in addition to code for primary procedure) (use 338X7 in conjunction with 338X3, 338X4, 338X5, 338X6)*). The RUC recommendation is the survey median and appears to be high compared to codes with similar times. We are proposing the survey 25th percentile work RVU of 5.53. A work RVU of 5.53 is supported by a reference code—CPT code 57267. CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure*) has a work RVU of 4.88 and the same time of 45 minutes.

There are no direct PE inputs for CPT code 338X7.

(8) Percutaneous Arteriovenous Fistula Creation (CPT Codes 368X1 and 368X2)

In October 2021, the CPT Editorial Panel created CPT codes 368X1 (*Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and*

peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) and 368X2 (*Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation*) to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach. Previously, CPT coding did not account for percutaneous arteriovenous access creation, as current the CPT codes only describe an open surgical approach. Given that new technologies have been developed that allow for less invasive approaches that utilize percutaneous image-guided methods to approximate a target artery and vein using magnets or mechanical capture, we created HCPCS codes G2170 (*Percutaneous arteriovenous fistula creation (avf), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed*) and G2171 (*Percutaneous arteriovenous fistula creation (avf), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed*) in July 2020 that describe two approaches to percutaneous arteriovenous access creation. The RUC intends for CPT codes 368X1 and 368X2, which represent two percutaneous approaches to creating arteriovenous access for End-Stage Renal Disease (ERSD) patients during hemodialysis, to replace HCPCS codes G2170 and G2171, and has requested both G2170 and G2171 be deleted. For CY 2023, the RUC recommended a work RVU of 7.50 for CPT code 368X1, and a work RVU of 9.60 for CPT code 368X2.

We disagree with the RUC-recommended RVUs for CPT codes 368X1 and 368X2. We found that the recommended work RVUs were high when compared to other codes with similar time values. The RUC-recommended RVU of 7.50 for 368X1 is the second highest RVU for codes with 55 to 65 minutes of intraservice time and 94 to 114 minutes of total time, with RVUs ranging from 2.45 to 8.84. Similarly, the RUC-recommended RVU of 9.60 for 368X2 is the third highest RVU for codes with 65 to 85 minutes of intraservice time and 109 to 129 minutes of total time, with RVUs ranging from 4.69 to 10.95. Therefore, we are proposing a work RVU of 7.20 for CPT code 368X1, and a work RVU of 9.30 for CPT code 368X2.

We disagree with the RUC-recommended work RVU of 7.50 for CPT code 368X1 and are proposing an RVU of 7.20 that is based on the intra-service time ratio calculation using the second reference code from the RUC survey, CPT code 36905 (*Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*). The proposed RVU of 7.20 is based on the intra-service time ratio using the RUC-recommended 60 minutes intra-service time for CPT code 368X1 divided by 75 minutes of intra-service time for CPT code 36905, then multiplying by the RVU of 9.00 for CPT code 36905 ($(60/75) \times 9.00 = 7.20$). We chose to use the second reference code from the RUC survey, CPT code 36905, in this calculation because its intra-service time and total time values were closer to the time values proposed by the RUC for CPT code 368X1. We note that the RUC-recommended RVU of 7.50 is one of the highest values within the range of reference codes we reviewed with the same intra-service time and similar total time. The proposed work RVU of 7.20 is supported by the reference CPT codes we compared to CPT code 368X1 with the same 60 minutes of intra-service time and similar total time as CPT code 368X1; reference CPT code 47541 (*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (e.g., rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access*) has a work RVU of 6.75, and reference CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture*) has a work RVU of 8.84. Again, we believe 7.20 is a more appropriate value overall than 7.50 when compared to the range of codes with the same intra-service time and similar total time.

Although we disagree with the RUC-recommended work RVU of 9.60 for CPT code 368X2, we concur that the relative difference in work between CPT codes 368X1 and 368X2 is equivalent to the RUC-recommended interval of 2.10 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we are proposing a work RVU of 9.30 for CPT code 368X2, based on the RUC-recommended interval of 2.10 RVUs above our proposed work RVU of 7.20 for CPT code 368X1.

For the direct PE inputs, we are seeking additional information on two equipment items and four supply items. For two of those four supply items, we are requesting a justification for their inclusion as direct PE inputs. The RUC submitted invoices for two new equipment inputs; one for a Wavelinq EndoAVF generator (EQ403) used for CPT code 368X2, and the other for an Ellipsys EndoAVF generator (EQ404) used for CPT code 368X1. We are seeking comments and requesting information that may inform us why the Wavelinq generator (EQ403) is so much more expensive on its invoice as compared with the Ellipsys generator (EQ404) since the former costs $18,580 and the latter costs $3,000.

In addition, the RUC included supply items SD149 (catheter, balloon inflation device) and SD152 (catheter, balloon, PTA) as direct PE inputs for CPT codes 368X1 and 368X2. We are seeking comments and requesting information that may inform us if supply items SD149 and SD152 are typical, and how often they are used, for CPT codes 368X1 and 368X2. Also, the RUC included supply items SF056 (detachable coil) and SF057 (non-detachable embolization coil) as direct PE inputs for CPT code 368X2 (one each for SF056 and two each for SF057). We are seeking comments and requesting information that may provide us with a

justification for keeping supply items SF056 and SF057 as direct PE inputs for CPT code 368X2. We need to know if both of these supply items are typical and how often they are used for CPT code 368X2. If these supply inputs are not typical for these procedures, we believe that they should be removed from the direct PE inputs.

We are proposing to delete HCPCS codes G2170 and G2171 and replace them with CPT codes 368X1 and 368X2 as recommended by the RUC.

(9) Energy Based Repair of Nasal Valve Collapse (CPT Codes 37X01 and 30468)

In September 2021, the CPT Editorial Panel created CPT code 37X01 (*Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling*) which is currently reported with an unlisted code. For the January 2022 RUC meeting, both CPT code 37X01 and CPT code 30468 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)*) were reviewed. For CY 2023, the RUC recommended a work RVU of 2.70 for CPT code 37X01, and no change to the current work RVU of 2.80 for CPT code 30468.

The RUC reviewed the specialty society request to affirm the recent RUC valuations for CPT code 30468, which was surveyed and valued by the RUC in January 2020 for CY 2021. The RUC agreed, so for CY 2023, the RUC is not recommending any change to the current work RVU of 2.80 for CPT code 30468. In addition, the PE Subcommittee reviewed the direct practice expense inputs and made modifications to the pre-service clinical staff time to CPT code 30468 in accordance with current standards. There was a previous oversight in valuing the direct PE inputs for CPT code 30468. Therefore, 3 minutes of clinical staff time has been added to CPT code 30468 for clinical activity CA005 (complete pre-procedure phone calls and prescription).

We are proposing to maintain the current work RVU of 2.80 for CPT code 30468 as recommended by the RUC. We are also proposing the RUC-recommended direct PE inputs for CPT code 30468, which now includes clinical activity code CA005, without refinement.

For CPT code 37X01, the RUC recommended a work RVU of 2.70 based on a direct work RVU crosswalk from CPT code 31295 (*Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa*). We disagree with the RUC-recommended work RVU of 2.70. Therefore, we are proposing a work RVU of 2.44 for CPT code 37X01, which is the same RVU as CPT code 31297 (*Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium*) and has the same 20 minutes of intra-service time and similar total time. We note that CPT code 31295, which the RUC used as a direct crosswalk for the work RVU for CPT code 37X01, has the same 20 minutes of intra-service time and 56 minutes of total time as CPT code 31297. We believe the RUC should have used CPT code 31297 as the crosswalk for CPT code 37X01. Both CPT codes 31295 and 31297 were reviewed in 2017 and are in the same code family. The proposed work RVU of 2.44 is supported by the reference CPT codes we compared to CPT code 37X01 with the same 20 minutes of intra-service time and similar total time as CPT code 37X01; reference CPT code 31233 (*Nasal/sinus endoscopy, diagnostic; with maxillary sinusoscopy (via inferior meatus or canine fossa puncture)*) with an RVU of 2.18, and CPT code 31295 with an RVU of 2.70. Again, we believe 2.44 is a more appropriate value overall than 2.70 when compared to the range of codes with the same intra-service time and similar total time.

We are proposing the RUC-recommended direct PE inputs for CPT code 37X01 without refinement.

(10) Drug Induced Sleep Endoscopy (DISE) (CPT Code 42975)

In October 2020, the CPT Editorial Panel created CPT code 42975 (*Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic*) to report drug induced sleep endoscopy (DISE) flexible, diagnostic. At the January 2021 RUC Meeting, the RUC requested that this service be resurveyed for the April 2021 RUC Meeting using a standard 000-day survey template. For CY 2023, the RUC recommended a work RVU of 1.95 for CPT code 42975.

We disagree with the RUC-recommended work RVU of 1.95 for CPT code 42975 and are proposing a work RVU of 1.58. We believe the RVU should be lower than the RUC recommendation of 1.95 to reflect the decrease in total time from 68 minutes to 50 minutes. The proposed RVU of 1.58 is based on the total time ratio calculation using the RUC-recommended 50 minutes total time for CPT code 42975 divided by the 48 minutes of total time for CPT code 43197 (*Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*), then multiplying by the RVU of 1.52 for CPT code 43197 ((50/48) × 1.52 = 1.58). We found that CPT code 43197 has the same intra-service time and similar total time as CPT code 42975. Also, CPT code 43197 is a similar endoscopic procedure as CPT codes 42975 and 31579 (*Laryngoscopy, flexible or rigid telescopic, with stroboscopy*). We note that CPT code 31579 is the first key reference code in the RUC survey. The proposed work RVU of 1.58 is supported by the reference CPT codes we compared to CPT code 42975 with the same 15 minutes of intra-service time and similar total time as CPT code 42975; reference CPT code 43200 (*Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*) with an RVU of 1.42, and CPT code 62272 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)*) with an RVU of 1.58. Again, we believe the proposed RVU of 1.58 is a more appropriate value overall than 1.95 when compared to the range of codes with the same intra-service time and similar total time.

We are proposing the RUC-recommended direct PE inputs for CPT code 42975 without refinement.

(11) Endoscopic Bariatric Device Procedures (CPT Codes 43235, 43X21, and 43X22)

In February 2021, the CPT Editorial Panel created CPT codes 43X21 (*Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon*) and 43X22 (*Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)*) for endoscopic bariatric device procedures to the esophagogastroduodenoscopy (EGD) code family. CPT code 43235 (*Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*) is the base code for the EGD family and was surveyed with the new endoscopic bariatric device procedures, 43X21 and 43X22. All three of these CPT codes were reviewed at the April 2021 RUC meeting. For CY 2023, the RUC recommended an RVU of 3.11 for CPT code 43X21, an RVU of 2.80 for CPT code 43X22, and maintaining the current work RVU of 2.09 for CPT code 43235.

We are proposing the RUC-recommended work RVU of 3.11 for

CPT code 43X21, the RUC-recommended work RVU of 2.80 for CPT code 43X22, and maintaining the current work RVU of 2.09 for CPT code 43235 for this code family.

We are proposing the direct PE inputs for CPT code 43235 without refinement. However, we are proposing refinements to the direct PE inputs for CPT codes 43X21 and 43X22.

For CPT code 43X21, we are proposing refinements to the direct PE inputs for clinical labor activity codes CA001 (*complete pre-service diagnostic and referral forms) and CA011 (provide education/obtain consent*). We are proposing to refine CA001 from 5 minutes to the standard 3 minutes since no explanation was provided to support 5 minutes for this clinical labor activity. We are proposing to refine CA011 from 15 minutes to 10 minutes since it was not clear why this much time for education is needed, and we do not believe that the recommended 15 minutes would be typical for the procedure. Also, when we looked at other procedures with clinical labor activity code CA011 we did not find many procedures with more than 12 minutes for this activity. Therefore, we are proposing to refine the clinical labor activity times for CA001 and CA011 for CPT code 43X21 as described above, and to accept the remaining RUC-recommended direct PE inputs without refinement.

For CPT code 43X22, we are proposing a refinement to the direct PE input for clinical labor activity code CA016 (*prepare, set-up and start IV, initial positioning and monitoring of patient*) from 10 minutes to the standard 2 minutes. In the PE Summary of Recommendations for non-facility direct PE inputs provided by the RUC, the RUC recommended 8 minutes above the standard 2 minutes for CA016 and stated this clinical labor activity was identical to the 10 minutes for positioning the patient as CPT code 43260 (*Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*). However, our study of this code family could not find 10 minutes of non-facility direct PE inputs for clinical labor activity CA016. Also, CPT code 43260 is only performed in a facility and does not have any non-facility clinical labor times. Therefore, we are proposing to refine the clinical labor activity time for CA016 for CPT code 43X22 as described above, and to accept the remaining RUC-recommended direct PE inputs without refinement. This proposed reduction of 8 minutes to the CA016 clinical labor activity also carries over to the equipment times for the suction machine (Gomco) (EQ235), the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031), and the multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD) (ES087) which we are proposing to reduce by the same 8 minutes.

(12) Delayed Creation Exit Site From Embedded Catheter (CPT Code 49436)

CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) was finalized as potentially misvalued in the CY 2022 PFS final rule (86 FR 64996) and the code was found to be appropriate to value for the non-facility/office setting. The RUC only reviewed the PE inputs for this service at the January 2022 meeting. The RUC recommended 5 minutes for Clinical Activity Code CA013, line 34 in the non-facility/office setting on the RUC-recommended PE spreadsheet. We disagree with the RUC-recommended time, and are proposing the standard time of 2 minutes, as an adequate rationale was not provided for the additional time in the global space. This proposed reduction of 3 minutes to the CA013 clinical labor activity also carries over to the equipment times, which we are proposing to reduce by the same 3 minutes. Otherwise, we agreed with the RUC-recommended clinical labor times for activity codes CA011 and CA018, and we are proposing the remaining refinements as recommended.

The RUC did not recommend any work inputs for this code and we are not proposing any work RVU refinements.

(13) Percutaneous Nephrolithotomy (CPT Codes 50080, 50081)

In September 2021, the CPT Editorial Panel revised the descriptors to CPT codes 50080 (*Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (e.g., stone[s] up to 2 cm in a single location of kidney or renal pelvis, nonbranching stones)*) and 50081 (*Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (e.g., stone[s] > 2 cm, branching stones, stones in multiple locations, ureter stones, complicated anatomy)*), that in recent claims data were identified via the site of service anomaly screen, to be performed less than 50 percent of the time in the inpatient setting, but both codes have 090 day global periods, which include post-op inpatient hospital E/M services as a component of their value, typical of major surgery codes. The revised code descriptors also include image guidance and nephrostomy tube placement, which were not present in the old descriptors, and were reported as procedures that were separate from CPT codes 50081 and 50082. These codes have not been reviewed for nearly 30 years.

CPT code 50080 currently has a work RVU of 15.74 with 117 minutes of intra-service time and 359.5 minutes of total time. The RUC recommended a work RVU of 13.50, 90 minutes of intra-service time, and 244 minutes of total time for CPT code 50080, which represents a reduction from the current values. However, the recommended intra-service times dropped by 76.9 percent from the current intra-service time and the RUC recommended work RVU is reduced only by 85.9 percent. Therefore, we disagree with the RUC recommended work RVU and we are proposing a work RVU of 12.11 for CPT code 50080 with the RUC recommended 90 minutes of intra-service time and 244 minutes of total time. We note that our proposed work RVU for CPT code 50080 falls between CPT code 36830 (*Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (e.g., biological collagen, thermoplastic graft)*), with a work RVU of 12.03 and the same intra-service time of 90 minutes, and CPT code 36818 (*Arteriovenous anastomosis, open; by upper arm cephalic vein transposition*), with a work RVU of 12.39 and the same intra-service time of 90 minutes (and both with similar total times to CPT code 50080).

CPT code 50081 currently has a work RVU of 23.50 with 42 minutes of pre-service evaluation time, 0 minutes of pre-service positioning time, 25 minutes of pre-service scrub/dress/wait time, 195 minutes of intra-service time, 27 minutes of immediate post-service time, and 507.5 minutes of total time. The RUC recommended 22.00 work RVUs with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 140 minutes of intra-service time, 44 minutes of immediate post-service time, for a sum of 302 minutes of total time. The RUC-recommended intra-service time and total time for CPT code 50081 are less than the current times for this code and we expect the work RVUs to also be less than the current work RVUs.

Though the RUC recommended a work RVU of 22.00 that is less than the current 23.50 work RVU, a substantial reduction in time should be better reflected in the work RVU.

The RUC recommended 13.50 work RVUs for CPT code 50800 and 22.00 for CPT code 50081, with an incremental difference between the two codes of 8.50 work RVUs (22.00 − 13.50 = 8.50). We are proposing a work RVU of 20.61 for CPT code 50081, based on the proposed CPT code 50080's work RVU of 12.11 plus the RUC-recommended incremental difference 8.50 work RVUs between CPT code 50080 and CPT code 50081 (12.11 + 8.50 = 20.61).

We are proposing the direct PE inputs as recommended by the RUC for both codes in the family.

(14) Laparoscopic Simple Prostatectomy (CPT Codes 55821, 55831, 55866, and 558XX)

In October 2021, the CPT Editorial Panel added CPT placeholder code 558XX (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) and prompted this family of Laparoscopic Simple Prostatectomy codes for survey and review for the January 2022 RUC meeting.

The RUC recommends a work RVU of 15.18 for CPT code 55821 (*Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages*) with 33 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 120 minutes of intra-service time, and 25 minutes of immediate post-service time, for a sum of 329 minutes of total time. CPT code 55821 currently has a work RVU value of 15.76 with 102.0 minutes of intra-service time and 399.5 minutes of total time. After reviewing this code and relative similar codes in the PFS, we are proposing the RUC-recommended work RVU of 15.18 with 315 minutes of total time.

The RUC recommends a work RVU of 15.60 for CPT code 55831 (*Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal*), with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 10 minutes scrub/dress/wait time, 120 minutes of intra-service time, 25 minutes of immediate post-service time, for a sum of 329 minutes of total time. CPT code 55831 currently has a work RVU value of 17.19 with 114.0 minutes of intra-service time and 422.5 minutes of total time. The RUC notes an additional degree of difficulty with this retropubic incision approach (behind the pubis) compared to the suprapubic approach. After reviewing this code and relative similar codes in the PFS, we are proposing the RUC recommended work RVU of 15.60 with 322 minutes of total time.

The RUC recommends a work RVU of 22.46 for CPT code 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*) with 40 minutes of pre-service evaluation time, 15 minutes positioning time, 12 minutes scrub/dress/wait time, 180 minutes of intra-service time, 50 minutes of immediate post-service time, for a sum of 362 minutes of total time. CPT code 55866 currently has a work RVU value of 26.80 with 180 minutes of intra-service time and 422 minutes of total time. The RUC notes that this procedure removes the entire prostate with robotic assistance, and the complexity of nerve sparing when operating with a cancerous prostate, increases the medical complexity and intensity of this procedure. After reviewing this code and relative similar codes in the PFS, we are proposing the RUC recommended work RVU of 22.46 with 362 minutes of total time to CPT code 55866.

The RUC recommends a work RVU of 19.53 for CPT code 558XX (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) with 40 minutes of pre-service evaluation time, 8 minutes positioning time, 11 minutes scrub/dress/wait time, 180 minutes of intra-service time, 50 minutes of immediate post-service time, for a sum of 354 minutes of total time. The RUC offers CPT code 42420 (*Excision of parotid tumor or parotid gland; total, with dissection and preservation of facial nerve*) with a work RVU of 19.53, 180 minutes of intra-service time and 383 minutes of total time)) as a crosswalk to CPT code 558XX. After reviewing this code and relative similar codes in the PFS, we are proposing the RUC-recommended work RVU of 19.53 with 354 minutes of total time to CPT code 558XX.

We are proposing the RUC-recommended direct PE inputs for CPT codes 55821, 55831, 55866, and 558XX without refinement.

(15) Lumbar Laminotomy With Decompression (CPT Codes 63020, 63030, and 63035)

In October 2018, CPT code 63030 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*) was identified by the AMA as having an anomalous site of service when compared to Medicare utilization data. The Medicare data from 2014 through 2017 indicated that CPT code 63030 was performed less than 50 percent of the time in the inpatient setting, yet included inpatient hospital evaluation and management (E/M) services within its global period. In January 2019, the RUC recommended that this code be reviewed in 2 years (January 2021) to determine if previous changes to differentiate percutaneous, endoscopic, and open spine procedures were effective to correct reporting of this service. In December 2020, the Relativity Assessment Workgroup noted that CPT code 63030 continues to be primarily reported in the outpatient setting, but still includes inpatient hospital visits in its valuation. The specialty society indicated that there is still confusion about this code, and therefore, the RUC recommended that CPT code 63030 be referred to the CPT Editorial Panel to revise the descriptor to mitigate the incorrect reporting in the outpatient setting, but the CPT Editorial Panel did not accept the code change application to differentiate inpatient (63030) versus outpatient (630X0) at the September 2021 CPT meeting. Since this is a site of service issue, CPT code 63030 was surveyed with the code family for the January 2022 RUC meeting.

For CPT codes 63020 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical*), 63030, and 63035 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)*), we disagree with the RUC's recommended work RVUs of 15.95, 13.18, and 4.00, respectively, because they do not account for the surveyed changes in time for CPT codes 63020, 63030, and

63035, and the full application of the 23-hour policy to CPT code 63030. We are proposing a work RVU of 14.91 for CPT code 63020, a work RVU of 12.00 for CPT code 63030, and a work RVU of 3.86 for CPT code 63035.

The RUC recommends 40 minutes pre-service evaluation, 20 minutes pre-service positioning, 15 minutes pre-service scrub/dress/wait time, 90 minutes intraservice time, 30 minutes immediate post-service time, and one CPT code 99232 (*subsequent hospital care/day 25 minutes*), one CPT code 99231 (*Subsequent hospital care/day 15 minutes*), one CPT code 99238 (*Hospital discharge day management; 30 minutes or less*), one CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), and two CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter.*) visits in the post-operative period. This results in a 15-minute decrease in the pre-service period, a 30-minute decrease in intraservice time, a 5-minute decrease in immediate post-service time, and a 17-minute increase in the post-operative period. The proposed work RVU of 14.91 is based on the total time ratio calculation using the RUC-recommended 379 minutes of total time divided by the current total time of 412 minutes for CPT code 63020, then multiplying by the current work RVU of 16.20 for CPT code 63020 ((379 minutes/412 minutes) * 16.20 = 14.90). We note that this is a direct crosswalk to CPT code 27057 (*Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (e.g., gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral*), which has a work RVU of 14.91, identical intraservice and immediate post-service time of 90 minutes and 30 minutes, respectively, and only 10 more minutes of total time. We believe this work RVU more adequately accounts for the decrease in total and intraservice time than the RUC recommended work RVU, and we note that we considered the reverse building block methodology, which would result in a work RVU of 14.30, but we felt that it decreased the valuation of CPT code 63020 too much, considering the shift in post-operative work to include a longer, more intense office/outpatient visit (CPT code 99214).

We disagree with the RUC-recommended work RVU for CPT code 63030. More specifically, we disagree with the RUC recommended work RVU for CPT code 63030 because the RUC did not completely apply the 23-hour policy calculation (finalized in the CY 2011 PFS final rule (75 FR 73226)) in formulating its recommendations. Additionally, we disagree with the RUC recommended work RVU for this code for which the RUC considered the patient to be admitted during the post-operative period because the RUC did not fully apply the 23-hour policy when formulating their recommendations. As we noted in the CY 2011 PFS final rule (75 FR 73226), and as we discuss earlier in this section of this proposed rule (''(1) Anterior Abdominal Hernia Repair (CPT codes 157X1, 49X01, 49X02, 49X03, 49X04, 49X05, 49X06, 49X07, 49X08, 49X09, 49X10, 49X11, 49X12, 49X13, 49X14, and 49X15''), the work RVUs for services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment. Because such services are typically furnished in the outpatient setting, they should not be valued to include inpatient post-operative E/M visits. The level of discharge day management services included in the valuation of such services should similarly not reflect an inpatient discharge and should therefore be reduced. And finally, as discussed in CY 2011 rulemaking, the intraservice time from the inpatient level E/M postoperative visit should be reallocated to the immediate postservice time of the service. The 23-hour policy calculation, when fully applied to the calculation of a work RVU, is used to reduce the value of discharge day management services, remove the inpatient E/M visits, and reallocate the intraservice time to the immediate post-service period. We refer readers to the 2011 PFS final rule (75 FR 73226) for an in-depth explanation of the 23-hour policy.

For CPT code 63030, we believe the RUC only partially applied the 23-hour policy when it applied the policy to the immediate post service time, but not to the calculation of the work RVU. Instead, we believe the 23-hour policy should be fully applied to this code that describes outpatient services for which there is an overnight stay during the post-operative period, regardless of the number of nights that a patient stays in the hospital. The services to which the 23-hour policy is usually applied would typically involve a patient stay in a hospital for less than 24 hours, which often means the patient may stay overnight in the hospital. On occasion, the patient may stay in the hospital longer than a single night; however, in both cases (one night or more than one night), the patient is considered to be a hospital outpatient, not an inpatient, for Medicare purposes. In short, we do not believe that the work that is typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies, especially considering the previously discussed site of service anomaly for CPT code 63030.

In accordance with the 23-hour policy valuation methodology we established in the CY 2011 PFS final rule, we are instead proposing a work RVU of 12.00 for CPT code 63030.The steps are as follows:

- Step (1): 13.18 − 0.64* = 12.54.
- Step (2): 12.54 − 0.76** = 11.78.
- Step (3): 11.78 + (10 minutes × 0.0224)*** = 12.00 RVUs.

*Value associated with ½ hospital discharge day management service

**Value associated with an inpatient hospital visit, CPT code 99231.

***Value associated with the reallocated intraservice time multiplied by the post-service intensity of the 23-hour stay code.

The RUC recommends the maintenance of the current work RVU of 13.18 because there was no change in intraservice time and the 37-minute decrease in total time is largely due to the change in immediate post-service time and post-operative period from the application of the 23-hour policy. We note that the proposed work RVU of 12.00 is higher than the other valuations that we considered, including the total time ratio work RVU of 11.75 ((305 minutes/342 minutes) * 13.18 = 11.75) and the reverse building block work RVU of 11.45. We note that the proposed work RVU of 12.00 is well-bracketed by two 90-minute intraservice timed 090-day CPT codes 28725 (*Arthrodesis; subtalar*), with a work RVU of 11.22, and 58720 (*Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)*), with a work RVU of 12.16.

We note that, in the summary of recommendations (SOR) submitted to CMS by the RUC, the specialty societies assert that the surveyed total time would be the same as the current total

time if the 23-hour policy was not fully applied to the immediate post-service time and post-operative period, with only a shift of work from facility to office, but we note that this is not true. The surveyed total time is 339 minutes, but the RUC recommended 40 minutes for the pre-service evaluation time rather than the specialty societies' surveyed 45 minutes. If the RUC had recommended the survey times, with the pre-service evaluation refinement, the reverse building block work RVU would be 12.62, still less than the RUC-recommended work RVU of 13.18, effectively accounting for the shift from facility to office post-operative visits.

For CPT code 63035, we are proposing a work RVU of 3.86 based on the reverse building block methodology to account for the 11-minute increase in intraservice time. We note that this proposed value is between the surveyed 25th percentile value of 3.50 and the RUC-recommended work RVU of 4.00. We note that the proposed work RVU is well-bracketed by two 60-minute add-on CPT codes—CPT code 50706 and 63231. CPT code 50706 (*Balloon dilation, ureteral stricture, including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)*), has a work RVU of 3.80, and CPT code 63621 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)*), has a work RVU of 4.00.

For the direct PE inputs, we are proposing to remove the 125 minutes of equipment time for EQ168 (light, exam) for CPT codes 63020 and 63030 because the RUC contested the typicality of its use to assess the wound and remove staples. Because it is a standard piece of equipment in a neurosurgeon and orthopedic exam room, and the RUC questioned its typicality, we are proposing 0 minutes for EQ168 for CPT codes 63020 and 63030.

(16) Somatic Nerve Injections (CPT Codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 76942, 77002, and 77003)

In May 2021, the CPT Editorial Panel revised the descriptors and billing instructions for CPT codes 64415 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, including imaging guidance, when performed*), 64416 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 64417 (*Injection(s), anesthetic agent(s) and/or steroid; axillary nerve, including imaging guidance, when performed*), 64445 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, including imaging guidance, when performed*), 64446 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 64447 (*Injection(s), anesthetic agent(s); femoral nerve, including imaging guidance, when performed*), 64448 (*Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed*), 77002 (*Fluoroscopic guidance for needle placement*), 77003 (*Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)*) and 76942 (*Ultrasonic guidance for needle placement, imaging supervision and interpretation*). These codes were then surveyed by the RUC in October 2021.

We last finalized values for CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 64448 in the CY 2020 PFS final rule (84 FR 62744 through 62745). In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for codes in the somatic nerve injection family. At its October 2018 meeting, the RUC recommended work RVU and PE inputs for a number of somatic nerve injection codes, including CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 64448. (Note that in 2018, the codes did not include ''including imaging guidance, when performed'' in their descriptors.) During the October 2018 RUC presentation for this family of services, the specialty societies stated that CPT codes 64415, 64416, 64417, 64446, 66447, and 64448 were reported with the imaging code CPT code 76942 more than 50 percent of the time. In reviewing this family of services in the CY 2020 PFS final rule, our finalized work and PE values for the codes did not consider the simultaneous performance of injection and imaging (84 FR 62744). In May 2021, the CPT Editorial Panel revised the codes to include ''with imaging, when performed'' in the descriptors.

When presenting its CY 2023 valuation recommendations, the RUC pointed out that the current values and times for CPT codes 64415, 64416, 64417, 64445, 64446, 64447, and 6448 reflect only the work and time of the injection. The revised codes, however, include both injection and imaging. In order to make an equitable comparison between the RUC recommendations and the current values, the RUC suggested we compare the RUC recommendations to values that combined the current work and estimated time of the injection codes and the imaging code with which they are being bundled, CPT code 76942. We agreed with this approach and thank the RUC for providing combined work RVUs and estimated combined times, which we considered as part of the RUC's recommendations.

As part of its recommendations, the RUC reaffirmed its prior recommendations for a number of codes that were previously reviewed or reaffirmed in the CY 2020 PFS final rule, including: CPT codes 64400 (*Injection(s), anesthetic agent(s); trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular)*), 64408 (*Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), 64420 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level*), 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure)*), 64425 (*Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves*), 64430 (*Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve*), 64435 (*Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve*), 64449 (*Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)), and 64450 (Injection(s), anesthetic agent(s); other peripheral nerve or branch*) (84 FR 62744 through 62745); CPT code 64451 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography*) (84 FR 62740); and CPT code 64454 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*) (84 FR 62749). The RUC also reaffirmed its recommendation for CPT code 64455 (*Injection(s), anesthetic agent(s) and/or steroid; plantar common digital nerve(s) (e.g., Morton's neuroma)*), which was reviewed and valued in the CY 2019 PFS final rule (83 FR 58542). The codes the RUC wishes to reaffirm for CY 2023 have not been revised by the CPT Editorial Panel and were not resurveyed by the RUC since their prior valuation. Since we have not received new

information regarding these codes, we acknowledge the RUC's reaffirmation but are not reviewing the values of these codes at this time. We also note that the RUC-reaffirmed values for CPT codes 64435 (work RVU of 0.75), 64450 (work RVU of 0.75), 64451 (work RVU of 1.52), and 64454 (work RVU of 1.52) are the same as the current work RVUs that we finalized in the CY 2020 PFS final rule. The RUC reaffirmed work RVU of 0.94 for CPT code 64405 is the current work RVU, which was finalized in the CY 2019 PFS final rule (83 FR 59542) and reaffirmed in the CY 2020 final rule, and the RUC-reaffirmed work RVU of 1.10 for CPT code 64418 is the current work RVU value finalized in the CY 2018 PFS final rule (82 FR 53054) and reaffirmed in the CY 2020 PFS final rule. The RUC reaffirmed a work RVU of 0.75 for CPT code 64455 which is the current work RVU we finalized in the CY 2019 PFS final rule (83 FR 58542).

For CY 2023, we are proposing the RUC-recommended work RVUs for CPT codes 64417 (work RVU of 1.31), 64447 (work RVU of 1.34), 64448 (work RVU of 1.68), 77002 (work RVU of 0.54), 77003 (work RVU of 0.60), and 76942 (work RVU of 0.67).

For CPT code 64415, we disagree with the RUC-recommended work RVU of 1.50 and are proposing a work RVU of 1.35, based on the intraservice time ratio calculated using the ''combined'' values for CPT code 64415 and the imaging CPT code 76942 provided by the RUC. (The combined work RVU the RUC offered for comparison was 2.02 (the sum of the work RVUs for both codes: CPT code 64415 is 1.35 and CPT code 76942 is 0.67), and an estimated intraservice time of 15 minutes and total time of 43 minutes.) This proposed work RVU of 1.35 for CPT code 64415 is supported by a crosswalk to CPT code 11982 (Removal, non-biodegradable drug delivery implant), which has a work RVU of 1.34, an identical service time, and a total time that is two minutes lower than CPT code 64415. This value is further supported by a bracket of CPT codes: CPT code 64486 and CPT code 33285. CPT code 64486 (Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)) has a work RVU of 1.27 and identical intraservice and total time values to CPT code 64415, and CPT code 33285 (insertion, subcutaneous cardiac rhythm monitor, including programming) has a work RVU of 1.53, an intraservice time of 10 minutes and a total time of 40 minutes.

We note that when compared to the current time file for CPT code 64415, the RUC-recommended intraservice time decreased from 12 to 10 minutes (16.7 percent reduction) and RUC-recommended total time decreased from 40 to 35 minutes (12.5 percent reduction). However, the RUC-recommended work RVU increased by 0.15 which is an 11.1 percent increase. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should not be met with significant increases to work RVUs without adequate justification. Additionally, while we do acknowledge that adding imaging does bundle some additional work into the code, we do not believe that the recoding of the services in this family has resulted in a significant increase in their intensity, only a change in the way in which they will be reported, and through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve efficiencies via elimination of duplicative assumptions of the resources involved in furnishing particular services. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64415 actually decreased from the predecessor code. Thus, we are disinclined to ignore the impact of decreased times on the work RVU. We believe our proposed value of 1.35 appropriately reflects both the additional work and the decrease of time.

We considered proposing a work RVU of 1.27 for CPT code 64415, using CPT code 64486 as a comparison code, since it has the same intraservice and total times as the revised CPT code 64415. However, CPT code 64486, with a work RVU of 1.27, has a lower work RVU than the current work RVU of 64415 (1.35.) We are in general agreement with the RUC that it is important to acknowledge that there is some additional work that comes with adding imaging to this procedure.

For CPT code 64416, we disagree with the RUC-recommended work RVU of 1.80 and are proposing a work RVU of 1.65. While we disagree with the RUC's recommended work RVU, we did agree with the RUC's proposed increment of +0.30 between CPT codes 64415 and 64416. (The RUC recommendation for CPT code 64415 was 1.50, and the recommendation for CPT code 64416 was 1.80.) We found persuasive the RUC's observation that the current increment between CPT codes 64415 and 64416 is unusually small when compared to other sets of related codes in the family. Typically, the codes that add catheter placement in addition to the injection are 0.30–0.36 work RVUs higher than the codes for an injection in the same nerve group or region. Retaining such a narrow interval of 0.15 between CPT codes 64415 and 64416 would create a rank order anomaly within the family in light of adjustments to some of the other codes' work RVUs. Our proposed work RVU of 1.65 for CPT code 64416 is supported by a bracket of CPT codes: CPT code 64448 and CPT code 36573. CPT code 64448 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) has a work RVU of 1.60, 15 minutes intraservice time and 40 minutes total time, and CPT code 36573 (*Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older*) has a work RVU of 1.70, 15 minutes intraservice time and 40 minutes total time.

We note that, when compared to the current time file, the RUC-recommended intraservice time for CPT code 64416 decreased from 20 to 15 minutes (25 percent reduction) and the RUC-recommended total time decreased from 49 to 44 minutes (10.2 percent reduction). However, the RUC recommended a 0.32 increase in the work RVU, which is a 21.6 percent increase. We note that the RUC-recommended work RVU of 1.80 would give CPT code 64416 the highest work RVU of the surveyed codes, and would make it among the highest valued codes in the family. We do not believe the RUC-recommended work RVU appropriately accounts for the reductions in the surveyed total time for the procedure, and did not receive specific information explaining why, despite the decrease in time, the value should receive such a significant

increase relative to the other surveyed codes. As stated previously, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased significantly, decreases in time should be reflected in the revised work RVUs. As noted in our discussion of CPT code 64415 above, if the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64416, are now actually lower. We believe our proposed work RVU of 1.65 corrects the increment between CPT code 64415 and 64416, while also acknowledging that, the addition of imaging notwithstanding, the times for CPT code 64416 have noticeably decreased.

For CPT code 64445, we disagree with the RUC-recommended work RVU of 1.39 and are proposing a work RVU of 1.28, based on the intraservice time ratio calculated using the. ''combined'' values for CPT code 64445 and the imaging CPT code 76942 provided by the RUC. (The combined work RVU the RUC offered for comparison was 1.67 (the sum of the work RVUs for both codes: CPT code 64445 is 1.00 and CPT code 76942 is 0.67), and an estimated intraservice time of 13 minutes and total time of 27 minutes.) This proposed value of 1.28 is supported by a comparison to CPT code 64486 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)*), which has a work RVU of 1.27 and intraservice time of 10 minutes and total time of 35 minutes. The value is also supported by a low bracket of CPT code 58100 (*Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)*), with a work RVU of 1.21, identical intraservice time and almost identical total time, and a high bracket of CPT code 11982 (*Removal, non-biodegradable drug delivery implant*), with a work RVU of 1.34, identical intraservice time and a higher total time of 33 minutes.

We note that the RUC-recommended intraservice time and total time for CPT code 64445 are identical to the current intraservice and total times in the time file for CPT code 64445. However, the RUC recommended a 0.39 increase to the work RVU. We do not imply that the lack of change to the intraservice and total times means that the work RVU cannot be increased. We believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, the RUC-proposed increase in the work RVU does not seem justified. As noted in our discussion of CPT code 64415 above, if the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which in the case of CPT code 64445, are the same as the predecessor code.

We considered proposing a work RVU of 1.10 for CPT code 64445, using CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*) as a comparison code, with a work RVU of 1.10 and identical intraservice and total times as CPT code 64445. However, we believed this would cause a rank order anomaly within the family. For example, CPT code 64418 (*Injection(s), anesthetic agent(s) and/or steroid; suprascapular nerve*) also has a work RVU of 1.10, but does not include imaging. Again, we generally agree with the RUC that it is important to acknowledge the additional work that comes with adding imaging to this procedure, and to ensure that this additional work is reflected within the relative values of the family, but we are still proposing a work RVU of 1.28 for CPT code 64445.

For CPT code 64446, we disagree with the RUC-recommended work RVU of 1.75 and are proposing a work RVU of 1.64. This recommended work RVU is 0.36 higher than the proposed work RVU for CPT code 64445 (1.28). We note that the current increment between the current values of 64445 and 64446 (1.00 and 1.36, respectively) is 0.36. The RUC recommendations for these codes (1.39 and 1.75) preserved this increment. Since the same imaging activity is being added to both codes, we agree with preserving the relationship between the values of CPT codes 64445 and 64446. Our proposed work RVU of 1.64 for CPT code 64446 is supported by a bracket of CPT codes: CPT code 64448 and 36573. CPT code 64448 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) has a work RVU of 1.60, 15 minutes intraservice time and 40 minutes total time, and CPT code 36573 (*Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older*) has a work RVU of 1.70, 15 minutes intraservice time and 40 minutes total time. (We note that this is the same bracket we suggested to support the proposed value for CPT code 64416. As revised, the intraservice and total times for CPT codes 64416 and 64446 are the same.)

We note that, compared to the time file for CPT code 64446, the RUC-recommended intraservice time stayed the same (15 minutes) and the total time increased from 40 to 44 minutes (10 percent increase). The RUC-recommended work RVU for CPT code 64446, is 0.39 higher than the current RVU, a 28.7 percent increase. We believe the RUC-recommended work RVU increase is disproportionate to the change in time. Additionally, we note that the RUC-recommended times result in CPT code 64416 and CPT code 64446 having identical intraservice and total times. We believe it best preserves rank order within the family to assign CPT code 64416 and CPT code 64446 similar work RVUs.

We are proposing the direct PE inputs as recommended by the RUC for all of the codes in the Somatic Nerve Injections family.

(17) Transcutaneous Passive Implant-Temporal Bone (CPT Codes 69714, 69716, 69717, 69719, 69726, 69727, 69XX0, 69XX1, and 69XX2)

In October 2020, the CPT Editorial Panel deleted two codes used for mastoidectomy and replaced them with four new codes for magnetic transcutaneous attachment to external speech processor. The CPT Editorial Panel made additional revisions to differentiate implantation, removal, and replacement of the implants. The RUC submitted interim recommendations to CMS for six codes in this family following the January 2021 RUC meeting, and CMS proposed and finalized the recommended work RVU for all six of these codes in the CY 2022 PFS final rule (86 FR 65099 through 65100). For CY 2023, the CPT Editorial Panel established three additional new codes and the coding structure of the family was changed to describe the different techniques more appropriately for transcutaneous passive implant procedures that vary in time and intensity depending on the indication for the procedure, device chosen, and patient anatomy. The nine codes in the family were surveyed again for the January 2022 RUC meeting and new recommendations were submitted to CMS.

We are proposing the RUC-recommended work RVU for six of the nine codes in the Transcutaneous Passive Implant-Temporal Bone family.

We are proposing a work RVU of 9.03 for CPT code 69716 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor within the mastoid and/or resulting in removal of less than 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 9.97 for CPT code 69XX0 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 9.46 for CPT code 69719 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 10.25 for CPT code 69XX1 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*), a work RVU of 7.38 for CPT code 69727 (*Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 mm2 surface area of bone deep to the outer cranial cortex*), and a work RVU of 8.50 for CPT code 69XX2 (*Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 mm2 surface area of bone deep to the outer cranial cortex*).

We disagree with the RUC's recommended work RVU for the other three codes in the family for the procedures describing percutaneous attachment to external speech processor. We disagree with the RUC's recommended work RVU of 8.00 for CPT code 69714 (*Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we are instead proposing a work RVU of 6.68 based on a crosswalk to CPT code 38305 (*Drainage of lymph node abscess or lymphadenitis; extensive*). In reviewing CPT code 69714, we noted that the recommended intraservice time is decreasing from 40 minutes to 30 minutes (25 percent reduction), and the recommended total time is decreasing from 182 minutes to 146 minutes (20 percent reduction); however, the RUC-recommended work RVU is only decreasing from 8.69 to 8.00, which is a reduction of just over 8 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 69714, we believe that it is more accurate to propose a work RVU of 6.68 based on a crosswalk to CPT code 38305 to account for these decreases in the surveyed work time.

We also disagree with the recommended work RVU of 8.00 because it results in an intensity which is anomalously high in relationship to the rest of the code family. At the recommended work RVU of 8.00, the intensity of CPT code 69714 is increasing by nearly 50 percent as compared with the survey conducted last year, and the resulting intensity of the service would be significantly higher than any of the other codes in the family. We do not agree that this intensity would be typical given that the percutaneous form of implant described by CPT code 69714 should have the lowest intensity of the three types described in this code family. The implantation procedure described by this code should also typically have lower intensity than the revision/replacement procedures elsewhere in the family. We believe that the intensity of CPT code 69714 is more accurately described at our proposed work RVU of 6.68 based on a crosswalk to CPT code 38305. This code shares the same intraservice time of 30 minutes as CPT code 69714 and has a higher total time of 186 minutes; we agree that CPT code 69714 is more intense than CPT code 38305 which is offset by our crosswalk code having an additional office visit in its global period.

We disagree with the RUC's recommended work RVU of 8.48 for CPT code 69717 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we are instead proposing a work RVU of 7.91 based on a crosswalk to CPT code 46262 (*Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fistulectomy, including fissurectomy, when performed*). In reviewing CPT code 69717, we noted that although the intraservice time remains essentially unchanged (decreasing from 45 minutes to 44 minutes), the recommended total time is decreasing from 187 minutes to 159 minutes (15 percent reduction). However, the RUC-recommended work RVU is only decreasing from 8.80 to 8.48, which is a reduction of less than 4 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 69717, we believe that it is more accurate to propose a work RVU of 7.91 based on a crosswalk to CPT code 46262 to account for these decreases in the surveyed work time.

We also disagree with the recommended work RVU of 8.48 because it results in a higher intensity than the other two revision/replacement codes (CPT codes 69719 and 69XX1) in this family. CPT code 69717 describes the percutaneous form of implant which should have the lowest intensity of the three revision/replacement codes in this family, however at the recommended work RVU of 8.48 it would have the highest intensity of this group. While the intensity at the recommended work RVU for CPT code 69717 is nowhere near the anomalous nature of the intensity at the recommended work RVU for CPT code 69714, we still believe that the intensity would be more typical at the proposed work RVU of 7.91. This proposed valuation restores the relationship between the three revision/replacement codes by placing the intensity of CPT code 69717 slightly lower than CPT codes 69719 and 69XX1. Therefore, we believe that the intensity of CPT code 69717 is more accurately described at our proposed work RVU of 7.91 based on a crosswalk to CPT code 46262. This code has nearly the same intraservice time of 45 minutes as CPT code 69717 and has a higher total time of 179 minutes; we agree that CPT code 69717 is more intense than CPT code 46262 which is offset by our crosswalk code having an additional office visit in its global period.

We disagree with the RUC's recommended work RVU of 7.50 for CPT code 69726 (*Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor*) and we are instead proposing a work RVU of 6.36 based on a crosswalk to CPT code 67912 (*Correction of lagophthalmos, with implantation of upper eyelid lid load*

(e.g., gold weight)). In reviewing CPT code 69726, we noted that the recommended intraservice time is increasing from 30 minutes to 35 minutes (17 percent increase), and the recommended total time is increasing from 148 minutes to 150 minutes (1 percent increase); however, the RUC-recommended work RVU is increasing from 5.93 to 7.50, which is an increase of just over 26 percent. Although we did not imply that the increase in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected in modest increases to work RVUs. In the case of CPT code 69726, we believe that it is more accurate to propose a work RVU of 6.36 based on a crosswalk to CPT code 67912 to account for these increases in the surveyed work time.

We also disagree with the recommended work RVU of 7.50 because it results in an intensity which is anomalously high in relationship to the rest of the code family and creates a rank order anomaly within the work RVUs. CPT code 69726 describes the percutaneous form of the removal procedure which should have the lowest intensity of all nine codes in this family. However, the intensity of CPT code 69726 at the recommended work RVU of 7.50 would be the second-highest in the family, even higher than CPT code 69XX1 which describes the revision/replacement procedure with magnetic transcutaneous attachment resulting in removal of greater than or equal to 100 square mm surface area of bone. We do not agree that this would be typical and we believe that the intensity would be more accurate at our proposed work RVU of 6.36. We also note that the recommended work RVU of 7.50 for CPT code 69726 creates a rank order anomaly within the family as it would be higher than the recommended work RVU of 7.38 for CPT code 69727 which describes a more complex procedure and has higher surveyed work times. We therefore believe that the work and intensity of CPT code 69726 are more accurately described at our proposed work RVU of 6.36 based on a crosswalk to CPT code 67912. This code has nearly the same intraservice time of 40 minutes as CPT code 69726 and has a higher total time of 166 minutes; we agree that CPT code 69726 is more intense than CPT code 69726 which is offset by our crosswalk code having an additional office visit in its global period.

We are proposing the direct PE inputs as recommended by the RUC for all nine codes in the Transcutaneous Passive Implant-Temporal Bone family.

(18) Contrast X-Ray of Knee Joint (CPT Code 73580)

CPT code 73580 (*Radiologic examination, knee, arthrography, radiological supervision and interpretation*) was first identified via the high-volume growth screen in 2008. In 2021, the Relativity Assessment Workgroup (RAW) noted that code 73580 was never surveyed and remains CMS/Other sourced, and recommended that it be surveyed. CPT code 73580 was then surveyed. We are proposing the RUC-recommended work RVU of 0.59. We are also proposing the RUC-recommended direct PE inputs without refinement.

(19) 3D Rendering With Interpretation and Report (CPT Code 76377)

We nominated this code in the CY 2020 PFS final rule as potentially misvalued, stating that we believe it is of the same family as CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*), which was reviewed at the April 2018 RUC meeting. CMS requested that CPT code 76377 also be reviewed to maintain relativity within the code family (84 FR 62625). The specialty societies maintain that these services are more accurately viewed as separate code families. Furthermore, the RUC cites changes in technique and patient population as compelling evidence to maintain a physician work RVU of 0.79 despite a 5-minute recommended reduction in physician total time compared to the current physician time.

We are proposing the RUC recommended work RVU of 0.79 for CPT code 76377; however, we reiterate that we continue to believe that CPT code 76376 and 76377 would be more appropriately viewed as belonging to the same code family and we request that they be surveyed together.

We are proposing the RUC-recommended direct PE inputs without refinement.

(20) Neuromuscular Ultrasound (CPT Codes 76881, 76882, and 76XX0)

Since their creation in 2011, CPT codes 76881 (*Ultrasound, complete joint (ie, joint space and peri-articular soft-tissue structures), real-time with image documentation*) and 76882 (*Ultrasound, limited, joint or other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation*) have been reviewed numerous times as New Technology/New Services by the Relativity Assessment Workgroup (RAW). In October 2016, the RAW reviewed these codes and agreed with the specialty societies that the dominant specialties providing the complete (CPT code 76881) versus the limited (CPT code 76882) ultrasound of extremity services were different than originally thought, causing variation in the typical practice expense inputs. The RAW recommended referral to the Practice Expense Subcommittee for review of the direct practice expense inputs and the CPT Editorial Panel to clarify the introductory language regarding the reference to one joint in the complete ultrasound. The PE Subcommittee reviewed the direct practice expense inputs for CPT codes 76881 and 76882 and adjusted the clinical staff time at the January 2017 RUC meeting, and the CPT Editorial Panel editorially revised CPT codes 76881 and 76882 to clarify the distinction between complete and limited studies and revised the introductory guidelines to clarify reference to one joint in the complete ultrasound procedure in June 2017. In October 2021, the CPT Editorial Panel approved the addition of CPT code 76XX0 for reporting real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity, and the revision of CPT code 76882 to add focal evaluation. CPT codes 76881 and 76882 were identified as part of the neuromuscular ultrasound code family with CPT code 76XX0 and surveyed for the January 2022 RUC meeting.

For CPT codes 76881, 76882, and 76XX0, we disagree with the RUC-recommended work RVUs of 0.90, 0.69, and 1.21, respectively, as they do not account for the surveyed time changes or appropriate comparisons for the new add-on code, CPT code 76XX0, and are proposing a work RVU of 0.54 for CPT code 76881, a work RVU of 0.59 for CPT code 76882, and a work RVU of 0.99 for CPT code 76XX0.

CPT code 76881 represents a complete evaluation of a specific joint in an extremity. This service requires ultrasound examination of all the following joint elements: joint space (for example, effusion), peri-articular soft-tissue structures that surround the joint (that is, muscles, tendons, other soft-tissue structures), and any identifiable abnormality. In some circumstances, additional evaluations such as dynamic

imaging or stress maneuvers may be performed as part of the complete evaluation. The RUC recommended 5 minutes of pre-service time, 20 minutes of intraservice time, and 5 minutes of post-service time, based on the survey. The RUC discussed the 5-minute increase in intraservice time and determined that the increase relates to the change in the dominant specialty provider since the creation of the code, as previously there was 15 minutes of intraservice time for the radiologist to scan and/or review the sonographer-obtained images. Now, the rheumatologist is performing the scanning and it takes 20 minutes for the typical patient. For rheumatology, physicians typically scan the patients with portable ultrasound devices rather than utilizing sonographers as originally described in the 2010 survey. The RUC noted that this code is reported with an office E/M visit 58.9 percent and a non-facility office E/M visit 66.3 percent of the time; the RUC stated that CPT code 76881 is imaging-specific so the physician work described would not overlap with the E/M service, but we disagree, as the descriptions of pre-service and post-service work directly overlap. The description of pre-service work for CPT code 76881 states ''Review pertinent clinical information. Review any prior applicable imaging studies.'' Pre-service work for CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter.*), the most common E/M code reported with CPT code 76811, includes ''Review interval correspondence, referral notes, medical records, and diagnostic data generated since the last visit.'' Post-service work of CPT code 76881 is described as ''Discuss significant findings with the referring physician. Review and sign final report,'' whereas the post-service work for CPT code 99214 includes ''Arrange diagnostic testing and referral if necessary. Document the encounter in the medical record, spending time to further refine the differential diagnosis, workup, or treatment plan as necessary. Coordinate care by discussing the case with other physicians and members of the health care team and write letters of referral if necessary. Perform electronic data capture and reporting to comply with quality payment program and other electronic mandates. Review and analyze interval testing results and refine the differential diagnosis, workup, and treatment plan based on these results. Order additional testing based on these results. Communicate results and plan modifications with patient and/or family.'' We believe there is distinct overlap in pre-service and post-service work between the E/M visit and CPT code 76881, and therefore, we are proposing 0 minutes for the pre-service and post-service time rather than the RUC-recommended 5 minutes of pre-service and post-service time. The proposed work RVU of 0.54 is the reverse building block valuation based on the removal of the 5 minutes of pre-service and post-service time, with a long-standing intensity of 0.0224 (10 minutes * 0.0224 work/minute = 0.224 work RVUs). The proposed work RVU accounts for the 0.224 work RVU decrease as a result of the removal of pre-service and post-service time, and the increase of 5 minutes of intraservice time, while maintaining the same IWPUT of 0.027, as there was no discussed change in intensity. The specialty societies and the RUC asserted that there was an increase of 5 minutes as a result of the intraservice work changing due to a change in dominant specialty providing the service (from radiology to rheumatology), but did not present a change in intensity. We note that the specialty societies used CPT code 76700 (*Ultrasound, abdominal, real time with image documentation; complete*) with a work RVU = 0.81, 11 minutes of intra-service time, and 21 minutes total time, as a reference code because it has identical pre- and post-service time but less intra-service time than the surveyed code and is a clinically similar ultrasound code. We note that this is not an appropriate reference code as it is billed alone 72.8 percent of the time, and therefore, the valuation of CPT code 76700 accounts for pre- and post-service work that would not overlap with an E/M visit like the pre- and post-service work does for CPT code 76881.

CPT code 76882 represents a limited evaluation of a joint or focal evaluation of a structure(s) in an extremity other than a joint (for example, soft-tissue mass, fluid collection, or nerve[s]). This evaluation includes assessment of a specific anatomic structure(s) (for example, joint space only [effusion] or tendon, muscle, and/or other soft-tissue structure[s] that surround the joint) that does not assess all the elements included in CPT code 76881, although it does include all surrounding anatomy and any associated pathology or contralateral comparison as indicated. The RUC discussed the four-minute increase in intraservice time and determined that the increase relates to the change in dominant supplier of this service since the creation of the code, as there is currently 11 minutes of intraservice time that included scanning performed only by the podiatrist, and now the radiologist works with the sonographer to obtain and interpret the images in addition to the physician performing additional scanning as needed. Because radiologists no longer use portable ultrasound devices as originally described in the 2010 survey or in the 2017 PE update, the RUC and specialty societies assert that the physician work (time) has changed due to supervision of the sonographer in addition to the radiologist performing the scanning. The specialty societies and RUC also note that ultrasound technology has evolved immensely since 2010, including proliferation of high-frequency ultrasound probes dedicated to musculoskeletal imaging, as well as producing images with higher fidelity and more detail, whereby the number and quality of images that can be reviewed and the pathology to evaluate have greatly increased since 2010. Therefore, the typical patient requires 15 minutes of intraservice time. While we agree with the RUC that 15 minutes of intraservice time is warranted for CPT code 76882, we note there was no information indicating a change in intensity, and therefore, for CPT code 76882, we are proposing the reverse building block work RVU of 0.59 to account for the 4-minute increase in intraservice time and the maintenance of the current IWPUT of 0.024.

We note that commenters may raise concern about a potential rank order anomaly with the proposed work RVUs of 0.54 and 0.59 for CPT codes 76881 and 76882, respectively, but we note that the IWPUT of each code adequately reflects the increased intensity of intraservice work for the complete ultrasound (CPT code 76881; IWPUT = 0.027) versus the limited/focal ultrasound (CPT code 76882; IWPUT = 0.024), and the lesser work RVU of 0.54 for CPT code 76881 stems from the removal of the overlapping pre- and post-service time with the E/M visits that are typically performed. The RUC noted that consistency of intensity measures is demonstrated across the range of codes ascending from the limited code (CPT code 76881) to the new, most complex code (CPT code 76XX0). By proposing work RVUs that maintain the current IWPUTs, we maintain relativity both among the neuromuscular ultrasound family, as well as the larger family of ultrasound

imaging codes. We also note that the difference between the RUC-recommend IWPUTs and our proposed IWPUTs for CPT codes 76881 and 76882 is the same, where CPT code 76882 has an IWPUT that is 0.003 less than the IWPUT of CPT code 76881.

CPT code 76XX0 will be available for CY 2023 to report real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity. This code will examine a nerve throughout its length, within one extremity, including evaluation of multiple areas for potential nerve compression, measurement of cross-sectional areas, evaluation of echogenicity, vascularity, mobility including dynamic maneuvers when indicated, evaluation for any associated muscular denervation, with comparison to unaffected muscles or nerves within that extremity as needed. CPT code 76XX0 also requires permanently recorded images and cine loop and a written report containing a description of each of the elements evaluated. The RUC recommended 7 minutes of pre-service time, 25 minutes of intra-service time and 7 minutes of post-service time as supported by the survey. The RUC clarified that this service would not typically be reported with an office E/M visit. The RUC arrived at a recommended work RVU of 1.21 by comparing the pre-, intra-, and post-service times to those of CPT code 76881, which CMS is proposing to modify due to overlapping work in the pre- and post-service time with E/M visits. When we compared the proposed times of 0 minutes of pre-service time, 20 minutes of intraservice time, and 0 minutes of post-service time, and a work RVU of 0.54 for CPT code 76881, and the proposed times of 7 minutes of pre-service time, 25 minutes of intraservice time, and 7 minutes of post-service time for CPT code 76XX0, we arrived at a reverse building block work RVU of 0.99.

For the direct PE inputs, we are proposing to remove the 2 minutes of clinical labor time for CA006 (*Confirm availability of prior images/studies*), the 1 minute of clinical labor time for the CA007 (*Review patient clinical extant information and questionnaire*), and the 2 minutes for CA011 (*Provide education/obtain consent*) for CPT code 76881 because these RUC recommendations describe clinical labor activities that overlap with the E/M visit that is typically billed with CPT code 76881. We are proposing the direct PE inputs as recommended by the RUC for CPT codes 76882 and 76XX0.

(21) Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474)

Especially in the context of the current PHE for COVID–19, it is evident that consistent beneficiary access to vaccinations is vital to public health. As discussed in the CY 2021 PFS proposed rule (85 CFR 50162), many interested parties raised concerns about the reductions in payment rates for the preventive vaccine administration services that had occurred over the past several years. The codes for immunization administration services include CPT codes 90460, 90471, and 90473, as well as the three Healthcare Common Procedural Coding System (HCPCS) codes that describe the services to administer the Part B preventive vaccinations other than the COVID–19 vaccine: G0008 (influenza), G0009 (pneumococcal), and G0010 (HBV). Until CY 2019, we generally had established payment rates for these immunization administration services based on a direct crosswalk to the PFS payment rate for CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for the crosswalk code for CY 2018, and because the reductions in overall valuation for that code have been subject to the multi-year phase-in of significant reductions in RVUs, the payment rate for these vaccine administration codes has been concurrently reduced. Further, because the reduction in RVUs for the crosswalk code, CPT code 96372, was significant enough to be required to be phased in over several years under section 1848(c)(7) of the Act, the reductions in overall valuation for the vaccine administration codes were likewise subject to reductions over several years. As we noted in Table 21 of the CY 2022 PFS proposed rule (86 FR 39222), the national payment rate for administering these preventive vaccines has declined more than 30 percent since 2015.

We have attempted to address the reduction in payment rates for the Part B preventive vaccine administration HCPCS G-codes in the last three PFS rulemaking cycles. In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver these vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008, G0009 and G0010 (84 FR 62798).

In the CY 2021 PFS proposed rule, we proposed to crosswalk CPT codes 90460, 90471, and 90473, as well as HCPCS codes G0008, G0009 and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*) (85 FR 50163). In the proposed rule, we noted that CPT code 36000 is a service with a similar clinical vignette, and that the additional clinical labor, supply, and equipment resources associated with furnishing CPT code 36000 were similar to costs associated with these vaccine administration codes. We also noted that this crosswalk would have resulted in a payment rate for vaccine administration services that is approximately the same as the CY 2017 rate that was in place prior to the revaluation of CPT code 96372 (the original crosswalk code). In the CY 2021 PFS final rule, we did not finalize the proposed policy, and instead finalized a policy to maintain the CY 2019 payment amount for CPT codes 90460–90474, as well as HCPCS codes G0008, G0009 and G0010 (85 FR 84628). In the final rule, we also noted that we continued to seek additional information that specifically identifies the resource costs and inputs that should be considered to establish payment for vaccine administration services on a long-term basis.

For the CY 2022 rulemaking cycle, we requested feedback from interested parties that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act (influenza, pneumococcal, HBV, and COVID–19) for physicians, NPPs, mass immunizers and certain other providers and suppliers. We invited commenters to submit their detailed feedback to a series of questions and requests that we believed would assist us in establishing payment rates for these services that could be appropriate for use on a long-term basis; we direct readers to the full discussion of this topic in the CY 2022 PFS final rule (86 FR 65179 through 65193). For CY 2022, we finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine covered under the Medicare Part B preventive vaccine benefit at section 1861(s)(10) of the Act. We explained that since the administration of the preventive vaccines described under section 1861(s)(10) of the Act is not included within the statutory definition of physicians' services, the payment rates we established for these services in the

CY 2022 PFS final rule are independent of the PFS, and will be updated as necessary independently of the valuation of any specific codes under the PFS (86 FR 65186). We discuss the current payment policy for administration of preventive vaccines and our proposals for CY 2023 in section III.H. of this proposed rule.

We note that as we consider payment policies to ensure adequate access to the Part B preventive vaccines, including consideration of resource costs, the RUC surveyed and reviewed CPT codes 90460–90474 at the April 2021 meeting and submitted recommendations to CMS for our consideration in the CY 2023 rulemaking cycle.

We are proposing the RUC-recommended work RVU for all six codes in the Immunization Administration family. We are proposing a work RVU of 0.24 for CPT code 90460 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered*), a work RVU of 0.18 for CPT code 90461 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered*), a work RVU of 0.17 for CPT code 90471 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)*), a work RVU of 0.15 for CPT code 90472 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)*), a work RVU of 0.17 for CPT code 90473 (*Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)*), and a work RVU of 0.15 for CPT code 90474 (*Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)*).

For the direct PE inputs, we are proposing to remove 1 minute of clinical labor time for the CA008 (*Perform regulatory mandated quality assurance activity (pre-service)*) activity for CPT codes 90460 and 90471–90474. The RUC recommendations describe these activities as ''Checking historical and current temperatures for vaccine refrigerator; recording temperatures; reporting temperatures; vaccine inventorying; ordering vaccines; completing required Vaccines for Children (VFC) paperwork; receiving vaccines; inspecting/logging vaccines and putting them in the vaccine refrigerator; creating lot numbers in HER.'' Checking refrigerator temperatures, vaccine inventorying, and filling out vaccine paperwork are administrative tasks which are not individually allocable to a particular patient for a particular service. We are removing this 1 minute of clinical labor time as these administrative tasks are forms of indirect PE. We are also refining the equipment times for CPT codes 90460 and 90471–90474 to conform to our established policies for non-highly technical equipment.

In consideration of the information provided in the recommendation for these services, we are proposing the RUC's recommended work RVUs and direct PE inputs (with minor refinements) for these vaccine administration services. However, we continue to seek additional information from commenters that specifically identifies the resource costs and inputs that should be considered to establish payment for these vaccine administration services on a long-term basis, consistent with our policy objectives for ensuring maximum access to immunization services.

(22) Orthoptic Training (CPT Codes 92065 and 920XX)

In October 2019, the RUC identified CPT code 92065 (*Orthoptic and/or pleoptic training, with continuing medical direction and evaluation; performed by a physician or other qualified health care professional*) as needing review because it was Harvard Valued (that is, the value of the code had not been reviewed since the implementation of the Resource-Based Relative Value Scale (RBRVS)) and its utilization surpassed 30,000 in each of several recent years. At its January 2020 meeting, during review of CPT code 92065, the RUC noted that the use of ''and/or'' in the descriptor defined different patient populations and treatment techniques and recommended that the code be reviewed by the CPT Editorial Panel (CPT) in order to create two separate codes. Additionally, based upon review and analysis of survey data, specialty societies decided to submit a new code change application for the February 2021 CPT meeting.

During the February 2021 meeting, CPT noted that the services of CPT code 92065 are delivered in two different ways: directly by the practitioner and by a technician under the supervision of the practitioner. In response to this observation, CPT suggested that two codes be created to identify who furnishes the orthoptic service. Identifying in the code descriptor who furnishes the services would ensure more accurate valuation of both the work and the practice expense associated with the service. The CPT formally revised code 92065 and created new CPT code 920XX to describe orthoptic services furnished under the supervision of a physician or qualified health care professional.

During its April 2021 meeting, the RUC revalued the work associated with the services of CPT code 92065 (*Orthoptic training; performed by a physician or other qualified health care professional*) and valued the PE inputs for new CPT code 920XX (*Orthoptic training; performed by a physician or other qualified health care professional under supervision of a physician or other qualified health care professional*). CPT code 920XX is valued as a PE-only code.

After reviewing CPT code 92065, we are proposing to accept the RUC-recommended work RVU of 0.71. We also are proposing to accept the RUC-recommended direct PE inputs for CPT code 92065. We are proposing to accept the RUC-recommended direct PE inputs for CPT code 920XX as well.

(23) Dark Adaptation Eye Exam (CPT Code 92284)

CPT code 92284 (*Dark adaptation examination with interpretation and report*) was identified in July 2020 as Harvard Valued with a utilization of over 30,000 claims. In January 2021, the RUC recommended that the code be surveyed for the April 2021 RUC meeting. The RUC reviewed the survey results for the procedure and noted that the 25th percentile work value of 0.45 was greater than the code's current value. The RUC recommended a work RVU of 0.14, based on a direct work RVU crosswalk from CPT code 76514 (*Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)*). We disagree with the RUC-recommended work RVU of 0.14 for CPT code 92284. We found that the recommended work RVU did not adequately reflect reductions in physician time, since this diagnostic screening is usually completed during an E/M visit and largely consists of interpreting machine generated results. Instead, we are proposing a work RVU of 0.00 for CPT code 92284, which is comparable to other ophthalmic screening tests; such as 99172 (*Visual function screening, automated or semi-automated bilateral quantitative determination of visual acuity, ocular*

alignment, color vision by pseudoisochromatic plates, and field of vision (may include all or some screening of the determination[s] for contrast sensitivity, vision under glare)) and 99173 (*Screening test of visual acuity, quantitative, bilateral*). Alternatively, we considered using a total-time methodology with a work RVU of 0.03 and a reverse building block methodology with a work RVU of 0.06. We are seeking comments and requesting information that may inform why CPT code 92284 should include additional valuation as this procedure is included in an E/M visit.

For the direct PE inputs, we are proposing to refine the equipment time for the lens set (EQ165) from 24 minutes to 15 minutes and motorized table (EF030) from 24 minutes to 15 minutes. The reduction in time for both equipment types is proposed to match the RUC-recommended 15 minutes in Clinical Activity Code CA021. We are seeking public comment to provide further rationale for the additional 9 minutes recommended.

(24) Anterior Segment Imaging (CPT Code 92287)

For CPT code 99287 (*Anterior segment imaging with interpretation and report; with fluorescein angiography*), we are proposing the RUC-recommended work RVU of 0.40.

We are proposing the RUC-recommended direct PE inputs for CPT code 92287 without refinement.

(25) External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In the CY 2021 PFS proposed rule (85 FR 50164), we proposed to adopt the RUC's work RVU recommendations for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*), 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*), and 93248 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation*).

We noted that the recommendations for this family of codes contained one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item. Instead, we received pricing information from two sources: a weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Interested parties also submitted a series of invoices from the clinical study marketplace with a price of $595, which we rejected as we typically require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item.

After consideration of the information, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we received pricing information to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. We believed the kit to be the closest match from a pricing perspective to employ as a proxy until we would be able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply. In response to our proposal, we received conflicting information from commenters and in the CY 2021 PFS final rule (85 FR 84631), we ultimately finalized contractor pricing for CY 2021 for the four codes that included this supply input (CPT codes 93241, 93243, 93245, and 93247) to allow additional time to receive more pricing information.

We noted that interested parties have continued to engage with CMS and the MACs on payment for this service. We remained concerned that we continued to hear that the supply costs as initially considered in our CY 2021 PFS proposal were much higher than they should be. At the same time, we also heard that the resource costs, as reflected in the contractor-based payments, do not adequately cover the incurred cost for the SD339 supply that is used to furnish these services. In consideration of continued access to these services for Medicare beneficiaries, we once again solicited public comments and information in the CY 2022 PFS proposed rule (86 FR 39179) to support CMS' future rulemaking to establish a uniform national payment that appropriately reflects the PE inputs that are used to furnish these services. During the comment period, we received invoices and additional information for use in pricing the SD339 supply from the commenters.

Based on this information, we finalized an updated price of $200.15 for the extended external ECG patch, medical magnetic tape recorder'' (SD339) supply in the CY 2022 PFS final rule based on the average of the ten invoices we received (86 FR 65125). We believed that the invoice data for this supply item, which ranged from a minimum price of $179.80 to a maximum price of $241.99, suggested that our updated price of $200.15 was more accurate than the suggested crosswalk to the SD214 supply at a price of $325.98. We believed that considering a potential impact to payment for other services under the PFS, a proposal to establish national payment for these services based on this new pricing information should take into account broader feedback from interested parties. Therefore, we did not finalize national pricing at this time and finalized our proposal to maintain contractor pricing for CPT codes 93241, 93243, 93245, and 93247 for CY 2022.

For CY 2023, we received a series of additional invoices for the SD339 supply from two impacted parties. Each of the invoices priced the supply item at either $265.00 or $226.38; we are therefore proposing to average together these prices and establish a proposed price of $245.69 for the SD339 supply. We believe that this represents the most typical price for the supply based on the invoice data that has been provided over the past 2 years. We are also proposing

national pricing for CPT codes 93241, 93243, 93245, and 93247 for CY 2023 now that the SD339 supply has an established price. The proposed CY 2023 RVUs for these CPT codes are displayed in Addendum B on the CMS website under downloads for the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

(26) Cardiac Ablation (CPT Codes 93653, 93654, 93655, 93656, and 93657)

The technologies and clinical practices associated with Cardiac Ablation Services have changed enough over the past decade (since 2011 when they were first developed) that the specialty societies recommended referring theses codes to the CPT Editorial Panel to have the code descriptors for Cardiac Ablation Services updated to create new and more complete descriptors reflecting the fact that many of these services are commonly performed together and should be incorporated and bundled. From the survey results presented to CMS last year, the RUC advisory committee believes that many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to understand that services that are separately billed, were now combined into the existing codes (since CPT did not issue new codes for the revised descriptors). Since then, the RUC has re-surveyed these Cardiac Ablation codes in April 2021 for re-review. In the interim, the work RVUs for the newly bundled CPT codes were maintained at their current values until the new recommendations were presented for CY 2023.

The RUC re-surveyed and reviewed CPT code 93653 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry*), and recommends a work RVU of 15.00 with 31 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 120 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 199 minutes of total time. CPT code 93653 currently has a work RVU value of 14.75 with 23 minutes of pre-service evaluation time, 1 minutes positioning time, 5 minutes scrub/dress/wait time, 180 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 239 minutes of total time. The time and the physician's work of CPT add-on code 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure*) with a work RVU of 5.23 and 90 minutes of total time, and CPT add-on code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)*) with a work RVU of 1.50 and 20 minutes of total time are bundled within CPT code 93653. When all three codes are separately considered, they currently sum up to 21.48 work RVUs, much greater than the 15.00 work RVUs that the RUC has recommended. These codes also add up to much more physician total time than the RUC-recommended 199 minutes.

After reviewing this code and relative similar codes in the PFS, we propose a comparator CPT code 37229 (*Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed*) with a work RVU of 13.80 and a similar intra-service time of 120 minutes and similar pre-service evaluation, pre-service positioning, pre-service scrub/dress/wait times, and immediate post-service times, for a sum of 188 minutes of total time for a 000 day global period, compared to the RUC-recommended 199 minutes of total time for CPT code 93653. We propose a work RVU of 13.80 for the bundled CPT code 93563.

The RUC re-surveyed and reviewed CPT code 93654 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed*), and recommends a work RVU of 18.10 with 40 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 200 minutes of intra-service time, 33 minutes of immediate post-service time, for a sum of 291 minutes of total time. CPT code 93654 currently has a work RVU value of 19.75 with 23 minutes of pre-service evaluation time, 1 minutes positioning time, 5 minutes scrub/dress/wait time, 240 minutes of intra-service time, 40 minutes of immediate post-service time, for a sum of 309 minutes of total time. CPT code 93654 is currently and continues to be a bundled code. The RUC recommended intra-service times and total times for CPT code 93654 are less than the current times for this code, and the RUC-recommended work RVUs are also less than the current work RVUs. Though the RUC recommended a work RVU of 18.10, it is still a relatively high value compared to the existing 19.75 value. The RUC recommended a work RVU of 15.00 for CPT code 93653, and 18.10 for CPT code 93654, with a relative increment between them of 3.10 work RVUs. We are proposing to maintain the relative increment RVU difference of 3.10 between CPT code 93653 and CPT code 93654, so because we are proposing a work RVU of 13.80 for CPT code 93653, we are proposing a work RVU of 16.90 (13.80 plus 3.10) for CPT code 93654, with 200 minutes of intra-service time and 291 minutes of total time.

CPT add-on code 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)*) has a current work RVU of 5.50 with a physician intra-service time of 60 minutes as finalized last year, from a previous value of 7.50 work RVUs with 90 minutes of physician intra-service time. The RUC recommended the re-surveyed intraservice time of 60 minutes and 7.00 work RVUs. The primary change to CPT code 93655 is the reduction of the intraservice time of about 67 percent, which we use as a guide to determine a work RVU. We compare CPT add-on code 22854

(*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*), also with 60 minutes of intraservice and total time and a work RVU of 5.50 to CPT add-on code 93655 and we believe that this is a more accurate valuation than the RUC's work RVU comparison to CPT add-on code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)*) with a work RVU of 8.00 and an intra-service and total time of 60 minutes, and to CPT add-on code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 7.00 and an intra-service and total time of 60 minutes. After reviewing this code and relative similar codes in the PFS, we propose to maintain the current work RVU for CPT code 93655 of 5.50 with a physician intra-service time of 60 minutes, as finalized last year (86 FR 65108).

The RUC re-surveyed and reviewed CPT code 93656 (*Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed*), *and* recommends a work RVU of 17.00 with 35 minutes of pre-service evaluation time, 3 minutes positioning time, 15 minutes scrub/dress/wait time, 180 minutes of intra-service time, 30 minutes of immediate post-service time, for a sum of 263 minutes of total time. CPT code 93656 currently has a work RVU of 19.77 with 23 minutes of pre-service evaluation time, 1 minute positioning time, 5 minutes scrub/dress/wait time, 240 minutes of intra-service time, 40 minutes of immediate post-service time, for a sum of 309 minutes of total time. CPT code 93656 has bundled within it, the time and the physician's work of CPT add-on code 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure*) with a work RVU of 5.23 and 90 minutes of total time and CPT add-on code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)*) with a work RVU of 1.44 and 25 minutes of total time. When all three codes are separately considered, they sum up to 26.44 work RVUs, which is much greater than the 17.00 work RVUs that is recommended and has much more physician total time than the RUC recommended 263 total time minutes.

The RUC recommended intra-service times and total times for CPT code 93656 that are less than the current times for this code and we expect the work RVUs to also be less than the current work RVUs. Though the RUC recommended a work RVU of 17.00, it is still a high value compared to the existing 19.77. The RUC recommended the work RVU for CPT code 93653 as 15.00, and for CPT code 93656 as 17.00, with a relative increment between them of 2.00 work RVUs. As a better valuation for CPT code 93656, CMS proposes the proposed CPT code 93653's 13.80 work RVU plus the relative increment RVU difference of 2.00 that the RUC is maintaining between CPT code 93653 and CPT code 93656 (15.00 subtracted from 17.00 equals 2.00). This would value CPT code 93656 at 15.80 (13.80 plus 2.00) work RVUs for 180 minutes of intra-service time and 263 minutes of total time, which we propose for CY 2023.

CPT add-on code 93657 (*Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)*) has a current work RVU of 5.50 with a physician intra-service time of 60 minutes as finalized last year (86 FR 65108). The previous work RVU was 7.50 with 90 minutes of physician intraservice time. The RUC recommended the re-surveyed intra-service time of 60 minutes and 7.00 work RVUs. The primary change to CPT add-on code 93657 is the reduction of the intra-service time from before the re-survey and the current RUC-recommended time, from 90 minutes to 60 minutes, which is a reduction of about 67 percent, and which we used as a guide to determine an appropriate work RVU. We compare CPT add-on code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*), also with 60 minutes of intra-service and total time, and a work RVU of 5.50, to CPT add-on code 93657, and believe that this is a more accurate comparison for valuation than the RUC's work RVU comparison to CPT add-on code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)*) with a work RVU of 8.00 and an intra-service and total time of 60 minutes, and to CPT add-on code 34820 (*Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 7.00 and an intra-service and total time of 60 minutes. After reviewing this code and relative similar codes in the PFS, we are proposing to re-affirm the current work RVU of 5.50 with a physician intraservice time of 60 minutes for CPT add-on code 93657, as finalized last year (86 FR 65108).

The RUC did not recommend, and we are not proposing, direct PE inputs for CPT codes 93653–93657.

(27) Pulmonary Angiography (CPT Codes 93XX0, 93XX1, 93XX2, 93XX3, 93563, 93564, 93565, 93566, 93567, and 93568)

In May 2021, the CPT Editorial Panel revised CPT code 93568 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure*) which resulted in the creation of four new related CPT add-on codes. CPT add-on codes 93563 to 93567 were surveyed with the four new codes, as part of the same code family.

The RUC surveyed and reviewed CPT code 93563 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart*

catheterization (List separately in addition to code for primary procedure)), and recommends a work RVU of 1.11 for 15 minutes of intra-service and total time for this add-on service. The current work RVU is 1.11 for 25 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64494 (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)*), with a work RVU of 1.00 for 15 minutes of intra-service and total time. CPT code 64494 is a good comparator in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93563. Therefore, we are proposing a work RVU of 1.00 and 15 minutes of intra-service and total time for add-on CPT code 93563.

The RUC surveyed and reviewed CPT code 93564 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (e.g., aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (e.g., internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization (List separately in addition to code for primary procedure)*), and recommends a work RVU of 1.13 for 18 minutes of intra-service and total time for this add-on service. The current work RVU is 1.13 for 25 minutes of intra-service and total time, so there is a reduction of 7 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 31632 (*Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (List separately in addition to code for primary procedure)*) with a work RVU of 1.03 for 18 minutes of intra-service and total time. CPT code 31632 is a good comparator in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93564. Therefore, we are proposing a work RVU of 1.03 and 18 minutes of intra-service and total time for add-on CPT code 93564.

The RUC surveyed and reviewed CPT code 93565 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (List separately in addition to code for primary procedure)*), *and* recommends a work RVU of 0.86 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.86 for 20 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)*) with a work RVU of 0.50 for 10 minutes of intra-service and total time. CPT code 64421 is a good comparator code in terms of both the new physician time and due to the proportional work RVU as compared to CPT code 93565. Therefore, we are proposing a work RVU of 0.50 and 10 minutes of intra-service and total time for add-on CPT code 93565.

The RUC surveyed and reviewed CPT code 93566 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)*) *and* recommends a work RVU of 0.86 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.86 for 20 minutes of intra-service and total time, so there is a reduction of 10 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)*) with a work RVU of 0.50 for 10 minutes of intra-service and total time. CPT code 64421 is a good comparator code in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93566. Therefore, we are proposing a work RVU of 0.50 and 10 minutes of intra-service and total time.

The RUC surveyed and reviewed CPT code 93567 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)*), and recommends a work RVU of 0.97 for 10 minutes of intra-service and total time for this add-on service. The current work RVU is 0.97 for 15 minutes of intra-service and total time, so there is a reduction of 5 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 74248 (*Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic examination)*) with a work RVU of 0.70 for 10 minutes of intra-service and total time. CPT code 74248 is a good comparator code in terms of both the new physician time and due to the proportional work RVU, as compared to CPT code 93567. Therefore, we are proposing a work RVU of 0.70 and 10 minutes of intra-service and total time.

The RUC surveyed and reviewed CPT code 93568 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure)*), and recommends a work RVU of 0.88 for 13 minutes of intra-service and total time for this add-on service. The current work RVU is 0.88 for 20 minutes of intra-service and total time, so there is a reduction of 7 minutes in physician time. With the reduction of physician time, it is typical that there would be some reduction in the work RVUs. After reviewing this code and relative similar codes in the PFS, we agree with the RUC recommendation and are proposing a work RVU of 0.88 with 13 minutes of intra-service and total time for add-on CPT code 93568.

For the first of the related four new add-on codes to this family, temporarily designated as CPT placeholder code 93XX0 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral (List separately*

in addition to code for primary procedure)), the RUC recommends a work RVU of 1.05 for 11 minutes of intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 78434 (*Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)*) with a work RVU of 0.63 for 11 minutes of intra-service and total time. CPT code 78434 is a good comparator code in terms of both the physician time, and due to the proportional work RVU, as compared to CPT code 93XX0. Therefore, we are proposing a work RVU of 0.63 and 11 minutes of intra-service and total time for add-on CPT code 93XX0.

For the second of the related four new add-on codes to this family, temporarily designated as CPT placeholder code 93XX1 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral (List separately in addition to code for primary procedure)*), the RUC recommends a work RVU of 1.75 for 18 minutes of intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric and that this service is bilateral. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be HCPCS code G0289 (*Arthroscopy, knee, surgical, for removal of loose body, foreign body, debridement/shaving of articular cartilage (chondroplasty) at the time of other surgical knee arthroscopy in a different compartment of the same knee (List separately in addition to code for primary procedure)*) with a work RVU of 1.48 for 20.5 minutes of intra-service and total time and that this service is bilateral. G0289 has 2.5 minutes of additional physician intra-service time, so we adjust the comparator work RVU from 1.48 to 1.30. Therefore, we are proposing 1.30 work RVUs for 18 minutes of intra-service and total time for add-on CPT code 93XX1.

For the third of the related four new add-on codes to this family, temporarily designated as CPT placeholder code 93XX2 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization. (List separately in addition to code for primary procedure)*), the RUC recommends a work RVU of 1.84 for 20 minutes of intra-service and total time for this add-on service. The RUC noted that the typical patient for this service is pediatric. After reviewing this code and relative similar codes in the PFS, we believe a better comparator add-on code would be CPT code 93598 (*Measurement of output of blood from heart, performed during cardiac catheterization for evaluation of congenital heart defects (List separately in addition to code for primary procedure)*) with a work RVU of 1.44 for 20 minutes of intra-service and total time. CPT code 93598 is a good comparator code in terms of both the physician time, and due to the proportional work RVU, as compared to CPT code 93XX2.

Therefore, we are proposing 1.44 work RVUs for 20 minutes of intra-service and total time for add-on CPT code 93XX2.

For the last of the related four new add-on codes to this family, temporarily designated as CPT placeholder code 93XX3 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, each distinct vessel)*), the RUC recommends a work RVU of 1.92 for 20 minutes of intra-service and total time for this add-on service. The RUC describes this service and the physician's work as very time-intensive and complicated, and the typical patient for this service is pediatric. We agree with the RUC recommendations and are proposing a work RVU of 1.92 with 20 minutes of intra-service and total time for add-on CPT code 93XX3.

The RUC did not recommend, and we are not proposing, direct PE inputs for CPT codes 93563–93XX3.

(28) Quantitative Pupillometry Services (CPT Code 959XX)

The CPT Editorial Panel approved a new Category I CPT code to replace the sunset Category III (CPT code 0341T Quantitative pupillometry with interpretation and report, unilateral or bilateral) and 92499 (Unlisted ophthalmological service or procedure for reporting this service).

We are not proposing the RUC-recommended work RVU of 0.25 for CPT code 959XX, as we believe this is an overestimation based on a comparison to other codes with similar time values, particularly the key reference code CPT code 92081 (*Visual field examination, unilateral or bilateral, with interpretation and report; limited examination (e.g., tangent screen, Autoplot, arc perimeter, or single stimulus level automated test, such as Octopus 3 or 7 equivalent*). In the interest of maintaining relativity with similarly timed codes, we are instead proposing a work RVU of 0.18 with a crosswalk to CPT code 92504 (*Binocular microscopy (separate diagnostic procedure)*). We note that this value falls between the work RVUs of 0.17 for CPT code 94010 (*Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and 0.20 for CPT code 77081 (*Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)*); both codes have identical intraservice times and similar total times.

We are proposing the RUC-recommended direct PE inputs without refinement.

(29) Caregiver Behavior Management Training (CPT Codes 96X70 and 96X71)

CPT code 96X70 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; initial 60 minutes*) and its add-on code, CPT code 96X71 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; each additional 15 minutes (List separately in addition to code for primary service*)), are new codes created by the CPT Editorial Panel during its February 2021 meeting. The two codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's daily life. According to the CPT Summary of Recommendations, during the face-to-face time service time, caregivers are taught how to structure the patient's environment to support and reinforce

desired patient behaviors, to reduce the negative impacts of the patient's diagnosis on patient's daily life, and to develop highly structured technical skills to manage patient behavior.

As a means of identifying work values for CPT codes 96X70 and 96X71, three specialty societies sent surveys to a random sample of a subset of their members. Based upon survey results and after discussion, the RUC recommended a work RVU of 0.43 per identified patient service for CPT code 96X70. The RUC noted that this recommendation is based upon a median group size of six caregivers and includes 10 minutes pre-time, 60 minutes intra-time, and 20 minutes post-time for a total time of 90 minutes. For CPT code 96X71, the 15-minute add-on code, the RUC recommended a work RVU of 0.12, which is also based upon a median group size of six.

After reviewing the caregiver training codes, we have determined that CPT codes 96X70 and 96X71 are not payable under the PFS. Under section 1862(a)(1)(A) of the Act, Medicare payment is generally limited to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or that improve the functioning of a malformed body member. In past rulemaking, we have explained that we read section 1862(a)(1)(A) of the Act to limit Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an individual Medicare beneficiary's illness or injury or that improve the functioning of an individual Medicare beneficiary's malformed body member. For example, in the CY 2013 PFS final rule (77 FR 68979), when discussing payment for the non-face-to-face care management services that are part of E/M services, we stated that Medicare does not pay for services that are furnished to parties other than the beneficiary. We listed as an example, communication with caregivers. Because the codes for caregiver behavior management training describe services furnished exclusively to caregivers rather than to the individual Medicare beneficiary, we did not review the RUC-recommended valuation of these codes for purposes of PFS payment. However, recognizing our focus on ensuring equitable access to reasonable and necessary medical services, we are seeking comment about the services described by these two codes. First, we are seeking comment on the ways in which a patient may benefit when a caregiver learns strategies to modify the patient's behavior. We are also seeking comment on how current Medicare policies regarding these caregiver training services may impact Medicare beneficiary health. Finally, we are seeking comment about how the services described by these codes might be bundled into Medicare covered services as incident to services or as practitioner work that is part of some care management codes.

(30) Cognitive Behavioral Therapy Monitoring (CPT Code 989X6).

See the Remote Therapeutic Monitoring (RTM) section II.I. of this proposed rule for a review of new device code, CPT code 989X6.

(31) Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS Codes G0442 and G0444)

Interested parties have raised concerns with the portion of the code descriptors that require a certain number of minutes to bill for the HCPCS codes G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0444 (*Annual depression screening, 15 minutes*). Over the past several years, AAFP and the ACP have requested that CMS revise the code descriptors to state ''up to 15 minutes'' instead of the current ''15 minutes,'' allowing practitioners to efficiently furnish the service. As currently described, claims for the service are said to be denied by MACs in instances where records suggest that a full 15 minutes was not reached by the practitioner when furnishing the service. Both codes are high in volume for 2019 and 2020, with over 700,000 reported services in our Medicare claims data.

Medicare Part B coverage for such screenings originated from a national coverage determination (NCD) from 2011 and 2012. We believe that these screenings may not require a full 15 minutes to perform for the typical patient, so we believe that it would be appropriate to propose to revise the descriptors to specify that screening times of 5 to 15 minutes would be the typical range to furnish these services. This will establish a lower time limit for both HCPCS codes G0442 and G0444. Therefore, we propose to modify the descriptor for HCPCS code G0442 to read ''*Annual alcohol misuse screening, 5 to 15 minutes*'' and for HCPCS code G0444 to read ''*Annual depression screening, 5 to 15 minutes.*''

(32) Insertion, and Removal and Insertion of New 180-Day Implantable Interstitial Glucose Sensor System (HCPCS Codes G0308 and G0309)

For the CY 2021 PFS final rule (85 FR 84645), we established national pricing for 3 Category III CPT codes that describe continuous glucose monitoring. Category III CPT codes 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*), 0447T (*removal of implantable interstitial glucose sensor from subcutaneous pocket via incision*), and 0448T (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*) describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from a subcutaneous pocket. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provide glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The direct PE inputs for CPT code 0446T include a 90-day supply item, SD334 (implantable interstitial glucose sensor), and a 90-day smart transmitter proxy equipment item, EQ392 (heart failure patient physiologic monitoring equipment package). The direct PE inputs for CPT code 0448T include only the 90-day SD334 interstitial glucose sensor.

For CY 2022, based on requests from interested parties for CMS to allow beneficiaries critical access to a newly approved 180-day continuous glucose monitoring system, CMS established two new HCPCS codes to describe the new 180-day monitoring service. Specifically, CMS established HCPCS code G0308 (*Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training*) and G0309 (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation*). The newly approved 180-day continuous glucose monitoring system extends the monitoring period from the previous 90 days to allow for a longer monitoring period between replacement of the sensor. We believe it is important for beneficiaries to have continued access to this service during the transition from a 90- to 180-day monitoring period where the 90-day sensor may become obsolete. Therefore, HCPCS codes G0308 and G0309 are contractor priced and effective July 1, 2022. We are seeking information and invoices from

interested parties on the costs of the 180-day interstitial glucose supply and 180-day smart transmitter equipment direct PE inputs for HCPCS codes G0308 and G0309 to ensure proper payment for these physician's services, for consideration of national payment amounts for CY 2023. We note that the 90-day supply item, SD334, is currently priced at $1,500 based on information we received from interested parties. The 90-day smart transmitter, EQ392, is currently priced at $1,000 and assigned a time value of 25,290 minutes derived from 60 minutes per hour times 24 hours per day times 90 days per billing quarter divided by 1 minute of equipment use of every 5 minutes of time. HCPCS code G0308 includes the smart transmitter and interstitial glucose sensor and HCPCS code G0309 includes the interstitial glucose sensor only.

(33) Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2)

(a) Background and Proposal

In the CY 2022 PFS proposed rule (86 FR 39104, 39179–39181), we explored refinements to the PFS that would appropriately value chronic pain management and treatment (CPM) by soliciting comment on CPM for the purpose of future rulemaking. In our solicitation, we described Federal efforts for more than a decade to effectively address pain management as a response to the nation's overdose crisis,[9] such as the National Pain Strategy [10] and the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF) Report.[11] As we noted in our CY 2022 comment solicitation, several sections of the Support for Patients and Communities Act of 2018 [12] (SUPPORT Act) describe actions the Department of Health and Human Services has been directed to take to improve pain care, such as section 2003, which amended Medicare's Annual Wellness Visit [13] to include a review of factors for evaluation related to pain for patients using opioid medications; section 6086, the Dr. Todd Graham Pain Management Study; [14] and section 6032, which required CMS to furnish a Report to Congress and develop a related Action Plan to review coverage and payment policies in Medicare and Medicaid related to the treatment of opioid use disorder and for non-opioid therapies to help manage acute and chronic pain.[15] In the section 6032 Report and the Action Plan, CMS included a recommendation to explore the possibility of establishing a new bundled payment under the Medicare Physician Fee Schedule for integrated multimodal pain care that could include certain elements such as diagnosis, a person-centered plan of care, care coordination, medication management, and other aspects of pain care.

As described in Goal 3 of CMS's 2022 Behavioral Health Strategy [16] (Strategy), CMS intends to improve the care experience for individuals with acute and chronic pain, expand access to evidence-based treatments for acute and chronic pain, and increase coordination between primary and specialty care through payment episodes, incentives, and payment models. In late 2019, the CMS Office of Burden Reduction & Health Informatics launched the ''Chronic Pain Stakeholder Engagement'', which focused on understanding access to covered treatment and services for people living with pain.[17] CMS recently released information gathered from interested parties through this Engagement using qualitative research methods and the human-centered design process, to uncover provider burden, and identify opportunities to improve access to covered services by illustrating the experiences of people living with, and treating, chronic pain. The intent of this project was to highlight the most prominent barriers people with pain face in accessing care, and the factors influencing clinicians that can affect people with chronic pain, the quality of their care, and their quality of life.

In the context of the Biden-Harris' Administration's commitment to equity,[18] and the inclusion of equity as a pillar of CMS's Strategic Vision,[19] disparities exist in pain treatment due to bias in treatment, language barriers, and socioeconomic status. We are also aware that pain is a factor in suicidality and suicide, prioritized in the Surgeon General's Call to Action to Implement the National Strategy for Suicide Prevention [20] and in HHS's work to implement ''988,[21]'' the new national dialing code for suicide and crisis assistance to be implemented nationally this year.

In coordination with all of these initiatives, we also have continued to explore refinements to the PFS that would appropriately value CPM. In the CY 2022 PFS proposed rule, we sought comment on whether we should approach CPM through a standalone code or E/M add-on coding, and about the specific activities that are involved in CPM, how we might value such a code or service, the settings where this care is provided, the types of practitioners that furnish this care, and whether the service or any components of it could or should be furnished as ''incident to'' [22] services under the direction of the billing practitioner by other members of the care team (86 FR 39182). We received just under two thousand comments on this comment solicitation, including comments from national health care organizations including provider associations, federations, and societies that represent health care professionals; organizations that educate, connect, and advocate for people with pain; State-based health care organizations, medical societies and associations; cancer care centers; health care companies; device manufacturers; pain care providers; and people living with pain. Almost all commenters were supportive of our efforts to carefully consider an approach to coding and payment for care for CPM. Many commenters supported the creation of separate coding and payment for CPM under the PFS. We summarized these comments, expressed appreciation for the commenters' attention to informing our approach to payment and coding for comprehensive CPM services, and thanked the commenters for their comments in the CY 2022 PFS final rule (86 FR 65129).

Generally, commenters agreed that efforts are needed to effectively support the complex needs of beneficiaries with chronic pain. Commenters emphasized that there are numerous conditions giving rise to chronic pain and that people presenting with chronic pain respond variably to various treatment modalities, and often require longer office visit times, and longer follow-up coordinating care with social workers

[9] *https://www.hhs.gov/overdose-prevention/.*

[10] *https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf.*

[11] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[12] *https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf.*

[13] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html.*

[14] *https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence.*

[15] *https://www.cms.gov/sites/default/files/2022-4/SUPPORT%206032%20Action%20Plan_Final_061521_Clean.pdf.*

[16] *https://www.cms.gov/cms-behavioral-health-strategy.*

[17] *https://www.cms.gov/About-CMS/OBRHI.*

[18] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[19] *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[20] *https://www.hhs.gov/sites/default/files/sprc-call-to-action.pdf.*

[21] *https://www.samhsa.gov/find-help/988.*

[22] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMatters Articles/downloads/se0441.pdf.*

and case managers, mental and behavioral health support, communications with emergency department physicians and nurses, and numerous medication adjustments. One commenter stated that beneficiaries with complex chronic pain conditions may require a lot of time for correct dosing of medications and counseling, and that such time is not captured effectively using existing E/M codes. This commenter also believed that separate coding and payment for chronic pain management could help with better understanding of the treatment of chronic pain than when the service is reported with existing visit codes and would allow for valuation based on the resources involved in furnishing these specific services to people with chronic pain, enhancing the likelihood of appropriate payment, especially for non-face-to-face time involved with the service.

A few commenters expressed preference for using existing E/M codes and the creation of codes to be used in conjunction with E/M codes. One commenter suggested that CMS either clarify or modify existing codes so they can support services for patients with chronic pain or significant acute pain, as well as beneficiaries with a chronic disease and a behavioral health condition, stating that using the existing codes would avoid any concerns about overpayment for patients with both a chronic disease and pain, while also making it more feasible for small practices to employ care management staff and provide customized care management services for all the patients who need them.

One commenter who was agreeable with various approaches to payment suggested that the guidelines for Cognitive Assessment and Care Plan Services code 99483 include ''chronic pain syndromes'' in the ''assessment of factors that could be contributing to cognitive impairment'' and that these codes could be reported by physicians who consult with a pain specialist about their patient's pain. This commenter also suggested that Transitional Care Management could also potentially include pain management following inpatient care to help prevent acute pain from progressing to chronic pain. Other commenters also likened CPM services to chronic care management services. We believe that chronic care management codes, which, except for Principal Care Management, specify that the chronic condition being managed is expected to last at least one year or until death, would not properly describe the condition of many beneficiaries with chronic pain. For example, the 11th revision of the World Health Organization's International Classification of Diseases and Related Health Problems define chronic pain as persistent or recurring pain lasting longer than three months.[23]

Commenters included feedback about other specific activities involved in the management of patients with chronic pain in addition to those we specified in the comment solicitation. Commenters also identified codes that CMS might examine as models for payment, either as stand-alone timed codes or monthly bundles. Commenters suggested which practitioners should be able to bill such CPM codes, which practitioners should be able to furnish CPM services incident to the services of a physician or other practitioner, and expressed views on adding CPM services to the Medicare Telehealth Services List and obtaining beneficiary consent for CPM services.

We agree with commenters who believe that E/M codes may not reflect all the services and resources required to furnish comprehensive, chronic pain management to beneficiaries living with pain. While we agree in principle that it might be appropriate to establish bundled all-inclusive coding with monthly payment for a broader set of CPM services, we do not have data at the present time on the full scope of services and resource inputs involved in care for patients with chronic pain to support development of a proposed monthly bundled all-inclusive rate. We do believe that E/M codes do not appropriately reflect the time and other potential resources involved in furnishing comprehensive CPM for beneficiaries with chronic pain. Beginning in the CY 2014 PFS final rule (78 FR 74414 through 74427), we recognized that the resources involved in furnishing comprehensive care to patients with multiple chronic conditions are greater than those required to support care in a typical E/M service. In response, we finalized a separately payable HCPCS code GXXX1 (*Chronic Care Management (CCM) services furnished to patients with multiple (2 or more) chronic condition expected to last at least 12 months, or until the death of the patient; 20 minutes or more per in 30 days of chronic care management services provided by clinical staff and directed by a physician or other qualified health care practitioner*). The following year, in the CY 2015 PFS final rule (79 FR 67715 through 67730), we refined aspects of the existing CCM policies and adopted separate payment for CCM services under CPT code 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; Comprehensive care plan established, implemented, revised, or monitored*). In the CY 2017 PFS final rule (81 FR 80244), we adopted CPT codes 99487 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) and 99489 (*CCCM services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). Then, in the CY 2019 PFS final rule (83 FR 59577), we adopted a new CPT code, 99491 (*CCM services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*), to describe at least 30 minutes of CCM services performed personally by a

[23] *https://icd.who.int/en.*

physician or NPP. In the CY 2020 PFS final rule (84 FR 62690), we established payment for an add-on code to CPT code 99490 by creating HCPCS code G2058 (*CCM services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*). We also created two new HCPCS G codes, G2064 and G2065 (84 FR 62692 through 62694), representing comprehensive services for a single high-risk disease (that is, principal care management). In the CY 2021 PFS final rule (85 FR 84639), we finalized a RUC-recommended replacement code for HCPCS code G2058 with the identical descriptor, CPT code 99439, and assigned the same valuation as for G2058. For CY 2022, the RUC resurveyed the CCM code family, including CCCM and Principal Care Management (PCM), and added five new CPT codes: 99437 (*CCM services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99424 (*PCM services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*), 99425 (*PCM services for a single high risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure*), 99426 (*PCM, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*), and 99427 (*PCM services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*).

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who directly performs the services (that is, clinical staff, or the physician or NPP), and the time spent furnishing the services. The RUC-recommended values for work RVUs and direct PE inputs for these codes in CY 2022 were derived from a recent RUC specialty society survey. We proposed to accept the RUC-recommended values, considered public comments, and finalized the proposed values for the 10 CCM/CCCM/PCM codes.

In consideration of the supportive comments we received last year in response to our comment solicitation, clinical expertise within CMS, and internal input from CMS staff and from our HHS operating division partners, we are proposing to create separate coding and payment for CPM services beginning January 1, 2023. We recognize that there is currently no existing CPT code that specifically describes the work of the clinician who performs comprehensive, holistic CPM. We also believe the resources involved in furnishing CPM services to beneficiaries with chronic pain are not appropriately recognized under current coding and payment mechanisms. As noted above, we do not believe that E/M codes and values appropriately reflect time involved in furnishing CPM for beneficiaries with chronic pain. CMS has authority under section 1848 of the Act to establish codes that describe services furnished by clinicians and suppliers that bill for physicians' services, and to establish payment amounts for those services that reflect the relative value of the resources involved in furnishing them. We also expect that creating separate coding and payment for CPM will help facilitate the development of data regarding the prevalence and impact of chronic pain in the Medicare population, where conditions including osteoarthritis, cancer, and other similar conditions that cause pain over extended periods of time are common.[24] Such information can assist us in identifying potential coding and valuation refinements to ensure appropriate payment for these services. We also believe that the comprehensive care management involved in CPM services may potentially prevent or reduce the need for acute services, such as those due to falls [25] and emergency department care [26] associated with chronic pain, and also have the potential to reduce the need for treatment for concurrent behavioral health disorders, including substance use disorders. There is some evidence that addressing chronic pain early in its course may result in averting the development of ''high-impact'' chronic pain [27] in some individuals; these people report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain.

There are various definitions for chronic pain from, for example, the Centers for Disease Control and Prevention [28] and the National Institutes of Health,[29] and in the Institute of Medicine's (IOM) ''Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research'',[30] and in the World Health Organization International Classification of Disease Edition 11,—most define chronic pain consistently, with some variation, as pain that persists longer than three months. The CDC, for example, has defined chronic pain within its 2016 opioid prescribing Guideline as ''pain that typically lasts >3 months or past the time of normal tissue healing, and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.'' For clarity and operational use, we propose to define chronic pain as ''persistent or recurrent pain lasting longer than three months.'' We welcome comments from the public regarding whether this is an appropriate definition of chronic pain, or whether we should consider some other interval or description to define chronic pain. We are also interested in hearing from commenters about how the chronic nature of the person's pain should be documented in the medical record.

A monthly payment approach may also be more financially straightforward from the standpoint of beneficiaries receiving treatment for chronic pain, particularly with respect to applicable coinsurance, which is generally 20 percent of the payment amount, after the annual Part B deductible amount is met.[31]

Beginning for CY 2023, we are proposing to create two HCPCS G-codes to describe monthly CPM services. The codes and descriptors for the proposed G-codes are:

- HCPCS code GYYY1: *Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes;*

[24] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.*

[25] *https://www.cdc.gov/falls/facts.html.*

[26] *https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence.*

[27] *https://www.sciencedirect.com/science/article/pii/S1526590018303584?via%3Dihub.*

[28] *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.*

[29] *https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain.*

[30] *https://www.ncbi.nlm.nih.gov/books/NBK92525/#ch1.s3.*

[31] *https://www.medicare.gov/what-medicare-covers/what-part-b-covers.*

overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g., physical therapy and occupational therapy, and community-based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)

- HCPCS code GYYY2: *Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)*

We are interested in hearing from commenters regarding our proposed inclusion of ''administration of a validated pain assessment rating scale or tool,'' as an element of the proposed CPM services, and including it within the descriptor of the proposed HCPCS code GYYY1. We also solicit comment on whether a repository or list of such tools would be helpful to practitioners delivering CPM services.

We are proposing to include, as an element of the CPM codes, the development of and/or revisions to a person-centered care plan that includes goals, clinical needs, and desired outcomes, as outlined above and maintained by the practitioner furnishing CPM services.

We are proposing to include health literacy counseling as an element of the CPM codes because we believe it will enable beneficiaries with chronic pain to make well-informed decisions about their care, increases pain knowledge, and strengthens self-management skills. Health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.[32] Adequate health literacy may improve the person's capability to take responsibility for their health, including pain-related health issues such as adherence to treatment regimens and medication administration, and have a positive influence on health outcomes, and health disparities. CMS' Network of Quality Improvement and Innovation Contractors have used health literacy counseling to improve health counseling,[33] and health literacy counseling has been used to treat arthritis.[34] We are interested in hearing from commenters about how pain and health literacy counseling is or may be effectively used as a service element to help beneficiaries with chronic pain make well-informed decisions about their own care, weigh risks and benefits, make decisions, and take actions that are best for them and their health.

For HCPCS code GYYY1, we propose to include an initial face-to-face visit of at least 30 minutes, provided by a physician or other qualified health professional, to a beneficiary who has chronic pain, as defined above, or is being diagnosed with chronic pain that has lasted more than 3 months at the time of the initial visit. After consultation with our medical officers, we believe the management of a new patient with chronic pain would involve an initial face-to-face visit of at least 30 minutes due to the complexity involved with the initial assessment. We believe follow-up or subsequent visits could be non-face to face. HCPCS code GYYY2 describes an additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (listed separately in addition to GYYY1). We are seeking comment on the appropriateness of the proposed 30-minute duration per calendar month for GYYY1, and also on the proposed duration and frequency for GYYY2. We are also seeking comment on whether we should consider specifying a longer duration of time for GYYY1 (for example, one hour—or 45 minutes). Similarly, we seek comment on whether we should consider specifying a longer duration of time for GYYY2 (for example, 20-minute increments). We also welcome comment on our proposal to permit billing of CPM services for beneficiaries who have already been diagnosed with chronic pain, and for those who are being diagnosed with chronic pain during the visit.

We welcome comments regarding how best the initial visit and subsequent visits should be conducted (for example, in-person, via telehealth, or the use of a telecommunications system, and any implications for additional or different coding). We will also consider whether to add the CPM codes to the Medicare Telehealth Services List, based on our review of any information provided through the public comments and our analysis of how these new services may be appropriately furnished to Medicare beneficiaries. We are also asking for comment regarding whether there are components of the proposed CPM services that do not necessarily require face-to-face interaction with the billing practitioner, such as care that could be provided by auxiliary staff incident to the billing practitioner's services. For any components that could be furnished incident to the services of the billing practitioner, we request comment on whether these could be appropriately furnished under the general supervision of the billing physician or non-physician practitioner (NPP), for example, administration of a pain rating scale or tool, or elements of care coordination, as we have provided for certain care management services.

We believe that most CPM services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain. As calls for improved pain management have increased in recent years, this has resulted in better education and training of primary care practitioners and heightened awareness of the need for pain care nationally. We believe the codes we are proposing for CPM services will create appropriate payment for physicians and other practitioners (beyond primary care practitioners) that reflects the time and resources involved in attending comprehensively to the needs of beneficiaries with chronic pain. As the IOM ''Blueprint'' report noted, even people who need consultation with a pain specialist should benefit from the sustained involvement of a primary care practitioner who is able to help coordinate care across the full spectrum of health care providers, as such coordination ''helps prevent people from seeking relief from multiple providers and treatment approaches that may leave them frustrated and angry and worse off both physically and mentally, and from falling into a downward spiral of disability, withdrawal, and hopelessness.'' [35] The Blueprint stated that this type of fragmentation hinders the development of a strong, mutually trusting relationship with a single health professional who takes responsibility, and that this established relationship is one of the keys to successful pain treatment. We anticipate that if these

[32] *https://health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030#:~:text=Health%20literacy%20is%20a%20central,well-being%20of%20all.%E2%80%9D.*

[33] *https://qi.ipro.org/health-equity/health-literacy/.*

[34] *https://www.ahrq.gov/health-literacy/improve/precautions/1stedition/tool3.html.*

[35] *https://www.ncbi.nlm.nih.gov/books/NBK91497/.*

proposed codes are finalized, primary care practitioners will employ a variety of person-centered pain management strategies, such as those suggested in the PMTF Report and illustrated in CMS' CPM graphic [36] including medications, therapies, exercise, behavioral health approaches, complementary and integrative health, and community-based care based on the complexity, goals, and characteristics of each person they serve with chronic pain and according to the person-centered plan of care. It is also important to note that, in many parts of the country, people have access only to their primary care practitioner for chronic pain care.[37] We understand, however, the need or desire that some individuals with chronic pain have to be seen on an ongoing basis for CPM by a pain specialist who has received special training and/or certification to meet the needs of the most complex and challenging patients with chronic pain.

Therefore, we are proposing to permit billing by another practitioner after HCPCS code GYYY1 has already been billed in the same calendar month by a different practitioner. In these situations, we anticipate that there could be occasional instances where care of an individual with chronic pain is transferred to a pain specialist or other specialist during the same month they received the CPM services from a primary care practitioner, for ongoing care. In these or other situations (such as when the beneficiary elects to choose a different physician or practitioner to furnish CPM services), we would anticipate GYYY1 and potentially GYYY2 could be billed by another practitioner during the same month, for the same beneficiary. We believe that it would be unlikely for GYYY1 to be billed more than twice per month under such circumstances and are proposing placing a limit on the number of times the code could be billed per beneficiary per calendar month, at a maximum of twice per calendar month. We seek comment on our proposal to permit billing by another practitioner after the GYYY1 has already been billed in the same month by a different practitioner, and on the number of times the code could be appropriately billed per month, per beneficiary.

We propose to require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record, as not all Medicare beneficiaries with chronic pain eligible to receive these separately billable CPM services may understand or want to receive these services, and the beneficiary should be aware that they are receiving them. At the initial visit, the beneficiary with chronic pain should be educated regarding what the CPM services are, how often they may generally expect to receive the services, and have an explanation of any cost sharing that may apply in their particular situation. Practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of similar care management services, such as CCM services, and we are seeking comment on how best to effectively educate both practitioners and beneficiaries with chronic pain about the existence of, and the benefits and value of, the proposed CPM services. We are seeking comment regarding whether the initiating visit is the appropriate time for billing practitioners to obtain beneficiary verbal consent, if consent should be given at each visit, and also if beneficiary consent should be sought by the practitioners with whom CPM billing practitioners coordinate other Medicare services under the CPM plan of care, or even more broadly.

We believe there might be some potential for duplicative payment for services allocated to the same patient concurrent with certain other Medicare care management services, such as CCM or behavioral health integration (BHI) services; however, we believe the proposed CPM codes have features that would mitigate such circumstances, such as the elements of the service that specifically address the beneficiary's pain—for example, the administration of a validated pain rating scale or tool. We welcome comments regarding what, if any, Medicare services we should consider that could not be billed by the same practitioner for the same patient concurrent with any other Medicare services, to avoid duplication of payment, and help limit financial burden to the Medicare beneficiary with chronic pain. We note that we would expect to refine these codes as needed through future rulemaking as we receive more information how the codes are being used, and how they are implemented in practice.

To the extent that components of the proposed CPM codes are also components of other care management services, we reiterate our policy against double-counting time and require that the time used in reporting CPM services may not represent time spent in any other reported service. We propose that the CPM codes could be billed in the same month as a care management service, such as CCM, or BHI. We believe there are circumstances in which it is reasonable and necessary to provide both services in a given month, based on the needs of the Medicare beneficiary with chronic pain, for example, when the beneficiary has both chronic pain, and a mental disorder(s), or multiple chronic conditions. We are also proposing that the CPM codes would be able to be billed for the same Medicare patient in the same month as another bundled service such as HCPCS Codes G2086–G2088, which describe bundled payments under the PFS for opioid use disorders. We note that patient consent would need to be obtained for both of the bundled services such as, for example, CPM and BHI, and all other requirements to report CPM and to report the other service or services would need to be met. We invite comments on these billing proposals and their appropriateness in the context of CPM.

Finally, we are asking commenters whether we should consider creating additional coding and payment to address acute pain. We are interested in information regarding a definition for acute pain, standalone or E/M coding, the specific activities that could be furnished, how we might value and price such a code or service, the settings where care should be provided, the types of practitioners that should furnish acute pain care, if the service or any components should be furnished as ''incident to'' services under the direction of the billing practitioner or by other members of the care team, and other information that might help us in proposing such a code or codes.

(b) Valuation of Chronic Pain Management Services

Consistent with the valuation methodology for other services under the PFS, proposed HCPCS codes GYYY1 and GYYY2 would be valued based on what we believe to be a typical case, and we understand that, based on variability in patient needs, some patients will require more resources, and some fewer. The proposed CPM codes would separately pay for a specified set of CPM elements furnished during a month, including the administration of validated rating scales, establishment and review of a person-centered care plan that includes goals, clinical needs, and desired outcomes, and other elements as described in the proposed code descriptors. To value CPM, we compared the proposed services to codes that involve care management. In doing so, we concluded that the CPM services were similar in work (time and intensity) to that of PCM in that both the

[36] PLACEHOLDER FOR OBRHI GRAPHIC.

[37] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

PCM codes and proposed CPM codes reflect services that have similar complexities, possible comorbidities, require cognitive time on the part of the practitioner, and may involve coordination of care across multiple practitioners.

For HCPCS code GYYY1, we developed proposed inputs using a crosswalk to CPT code 99424 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*.), which is assigned a work RVU of 1.45. Additionally, for GYYY1 we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99424. We believe that the work and practice expense described by this crosswalk code is analogous to the services described in GYYY1, because GYYY1 includes similar *care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional,* as described in CPT code 99424.

We are proposing to value GYYY2 at a work RVU of 0.50, using a crosswalk to CPT code 99425 (*each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*) (*List separately in addition to code for GYYY1*), which is assigned a work RVU of 1.00. However, the required minimum number of minutes described in GYYY2 is half of the number of minutes in CPT code 99425. For HCPCS code GYYY2, we are proposing to use a crosswalk to half of the direct PE inputs associated with CPT code 99425. We believe that the work and practice expense described by this crosswalk code is analogous to the services described in GYYY2, because GYYY2 includes similar activities as described in CPT code 99425.

We are proposing that GYYY1 can only be billed when the full 30 minutes of service time has been met or exceeded. Additionally, we are proposing that the add-on code (GYYY2) can only be billed when the full 15 minutes of service time is met or exceeded.

Our proposed valuation of CPM services includes services that are personally performed by a physician (or other appropriate billing practitioner, such as a nurse practitioner (NP) or physician assistant (PA)) described by certain E/M visit codes that apply to a new patient in various settings. Accordingly, we are proposing that GYYY1/GYYY2 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 99202–99215 (*Office/outpatient visits new*), since these codes reflect face-to-face services furnished by the physician or other billing practitioner for related, separately billable services that are being furnished to a patient the practitioner has not previously seen. We believe it would be unlikely the practitioner is prepared to address the complex pain needs of a new patient on the same day he or she is seen for a general visit, or a visit where the person is being seen for some other illness or condition. We do not believe that the services included in GYYY1/GYYY2 would significantly overlap with CCM services; Transitional Care Management (TCM) services; or BHI services, which have various clinical purposes separate from CPM. We do believe there is likely overlap in the Medicare beneficiary population eligible to receive CCM, TCM, BHI, and the proposed CPM services, but we believe there are distinctions in the nature and extent of the assessments, care coordination, medication management, and care planning for CPM to allow concurrent billing for services that are medically reasonable and necessary, and that it is particularly important to allow for the provision of needed services, including behavioral health services to beneficiaries with chronic pain. We are soliciting comment on whether we have appropriately identified the codes Medicare should not pay if furnished during the same day as the proposed CPM codes, and if there are circumstances where multiple care planning codes could be furnished without overlap or other situations, such as where the practitioner is seeing a new patient.

We note that the proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings. We will consider for future rulemaking separately identifying and paying for CPM services furnished to beneficiaries in any appropriate setting of care, in recognition of the prevalence and burden of pain across all settings of care, and the associated time and service complexity to provide care for chronic pain. We appreciate comments on other settings where CPM services could be provided.

(c) Request for Comment

We believe there could be circumstances in which a beneficiary receiving CPM services needs referrals or recommendations, based on a clinician's assessment, for services or interventions that are not included as elements of the CPM services, such as for community-based care or physical and occupational therapy. We welcome comments on the care coordination that may occur between relevant practitioners furnishing services, such as complementary and integrative care, and on the community-based care element included in the descriptors for proposed GYYY1 and GYYY2.

Commenters may also wish to weigh in on how documentation of the performance of the elements of CPM services might best be addressed in medical recordkeeping. We are seeking general comment on whether there are any elements of CPM services outlined in this proposal that the public and interested parties believe are not typically furnished in connection with comprehensive chronic pain management, or any proposed elements of the CPM services that should be removed or altered. We also seek comment on whether there are elements of CPM services that we have not identified and should be added to the code descriptors.

Additionally, we are seeking comment on which, if any, CPM elements could be furnished as ''incident to'' services, and whether to add GYYY1 and GYYY2 to the list of services for which we allow general supervision as described in our regulation at § 410.26(b)(5). We welcome comments from the public for future rulemaking regarding what elements of the CPM services could be furnished under general supervision, or direct supervision. For example, facilitation and coordination of any necessary behavioral health treatment, chronic pain related crisis care, and ongoing communication and care coordination between relevant practitioners furnishing care might be appropriate activities to be considered under general supervision.

The proposed CPM codes may involve arrangements where the physician or

other health professional might work in collaboration with other health care providers or members of a care team, such as a psychologist, dental practitioner, or social worker, where these individuals might furnish certain elements of the service bundle under the direction of the physician or qualified health practitioner, such as assessments, person-centered care planning, referrals to community-based care, and other activities, as appropriate. We are requesting comments on if, and how, we should structure the proposed CPM code and payment for these services to account for these types of arrangements that could include team-based care.

(34) Proposed Revisions to the ''Incident to'' Physicians' Services Regulation for Behavioral Health Services

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we created an exception to our ''incident to'' regulation at § 410.26(b)(5) under which ''incident to'' services generally must be furnished under direct supervision. Specifically, we finalized a policy to require general, rather than direct, supervision when chronic care management services are furnished incident to the billing physician's or NPP's services outside of the practice's normal business hours by clinical staff. In the CY 2017 PFS final rule (81 FR 80255), we finalized a revision to our regulation under § 410.26(b)(5) to require a general, rather than direct, level of supervision for designated care management services, and established that we would designate care management services through notice and comment rulemaking.

We understand that circumstances related to the PHE for COVID–19 have likely contributed to an increase in the demand for behavioral health services while also exacerbating existing barriers to beneficiaries' access to needed behavioral health services. For example, the American Psychological Association (APA) conducted a survey in 2020 and a follow-up survey in 2021 to better understand the impact of the COVID–19 pandemic on mental health treatment and the work of practicing psychologists. In the 2021 follow-up survey, many psychologists reported increases in the demand for treatment of anxiety and depression. They reported the greatest increases in treating anxiety disorders (84 percent, up from 74 percent), depressive disorders (72 percent, up from 60 percent), and trauma- and stress-related disorders (62 percent, up from 50 percent). Other diagnoses with large increases included sleep-wake disorders, obsessive-compulsive and related disorders, and substance-related and addictive disorders.[38]

Additionally, according to HRSA's National Center for Health Workforce Analysis, by 2025, shortages are projected nationally for a variety of behavioral health practitioners, including psychiatrists; clinical, counseling, and school psychologists; mental health and substance use social workers; school counselors; and marriage and family therapists.[39] Currently, there is no separate benefit category under the statute that recognizes the professional services of licensed professional counselors (LPCs) and Licensed Marriage and Family Therapists (LMFTs). Therefore, payment for the services of LPCs and LMFTs can only be made under the PFS indirectly when an LPC or LMFT performs services as auxiliary personnel incident to, the services, and under the direct supervision, of the billing physician or other practitioner. According to the American Counseling Association, there are more than 140,000 licensed professional counselors (LPCs) in the U.S., and the Medicare program's reimbursement for mental health treatment services delivered by this professional group could address provider shortages.[40] Additionally, according to the U.S. Bureau of Labor Statistics, there were approximately 54,800 Marriage and Family Therapists (MFTs) as of May 2021.[41]

In the 2022 CMS Behavioral Health Strategy,[42] CMS included a goal to improve access to and quality of mental health care services. In light of the current needs among Medicare beneficiaries for improved access to behavioral health services, and the existing workforce shortages impeding access to needed treatment for behavioral health, we have considered regulatory revisions that may help to reduce existing barriers and make greater use of the services of LPCs and LMFTs. We note that CMS does not have authority to create a statutory benefit category for practitioner types. Therefore, we are proposing to amend the direct supervision requirement under our ''incident to'' regulation at § 410.26 to allow behavioral health services to be furnished under the general supervision of a physician or NPP when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. We are limiting the scope of this proposal to behavioral health services at this time due to increased needs for behavioral health treatment and workforce shortages in this field. We believe that this proposed change will facilitate utilization and extend the reach of behavioral health services. We believe that any risk associated with this proposed change would be minimal, since the auxiliary personnel providing the services would need to meet all of the applicable requirements to provide incident to services, including any applicable licensure requirements imposed by the State in which the services are being furnished, as described in § 410.26(a)(1).

(35) New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

In the CY 2017 PFS final rule (81 FR 80230), we established G-codes to describe monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99492–99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 through 53078). Additionally, we created a fourth G-code to describe services furnished using other models of BHI in the primary care setting, which was replaced by CPT code 99484 in the CY 2018 PFS final rule (82 FR 53077 through 53078).

We stated in the CY 2017 PFS final rule (81 FR 80236) that we recognized that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care. We finalized a code set to pay accurately for care furnished using this specific model of care, given its widespread adoption and recognized effectiveness. However, we stated we recognized that there are primary care practices that are incurring, or may incur, resource costs inherent to treatment of patients with similar conditions based on BHI models of care other than the psychiatric CoCM that may benefit beneficiaries with behavioral health conditions, and

[38] *https://www.apa.org/pubs/reports/practitioner/covid-19-2021.*

[39] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[40] *https://www.counseling.org/government-affairs/federal-issues/medicare-reimbursement.*

[41] *https://www.bls.gov/oes/current/oes211013.htm.*

[42] *https://www.cms.gov/cms-behavioral-health-strategy.*

therefore finalized a General BHI code which may be used to report a range of models of BHI services, and that we expected this code to be refined over time as we receive more information about other BHI models in use.

In the CY 2018 PFS final rule (82 FR 53078), we stated that we had received inquiries from interested parties about whether professionals who were not eligible to report the approved initiating visit codes for BHI services to Medicare might nonetheless serve as a primary hub for BHI services. For example, interested parties have suggested that a CP might serve as the primary practitioner that integrates medical care and psychiatric expertise. For purposes of future rulemaking, we sought comment on the circumstances under which this model of care is happening and whether additional coding would be needed to accurately describe and value other models of care. A few commenters suggested that CMS create separate codes to describe behavioral health care management services that could be billed by CPs and NPPs who are not authorized to bill Medicare for E/M services. One commenter suggested that CMS include psychiatric diagnostic evaluation services that can be furnished and billed by CPs as eligible initiating visits. Commenters also described other models of care that are in use, including the STAR–VA model and a model used in outpatient health care settings where a clinical social worker (CSW) not only furnishes psychiatric care but also assists with psychosocial aspects of medical care.

In the CY 2017 PFS final rule (81 FR 80239), we stated that we had received a few comments suggesting that in addition to the qualifying E/M services (or an AWV or IPPE), the initiating visit services for BHI should include in-depth psychological evaluations delivered by a CP including CPT codes 90791, 96116 or 96118, which include care plan development. In this final rule, we established that the same services that qualify as the initiating visit for CCM would also qualify as initiating services for BHI, which do not include in-depth psychological evaluation by a CP and which were not, in their entirety, within the scope of CPs' practice, and therefore, CPs would not be able to report the General BHI code directly (although a psychiatrist may be able to do so) (81 FR 80239).

In the 2022 CMS Behavioral Health Strategy,[43] CMS included a goal to improve access to and quality of mental health care services, and included an objective to ''increase detection, effective management and/or recovery of mental health conditions through coordination and integration between primary and specialty care providers.'' As previously noted in this proposed rule, we understand that circumstances related to the COVID–19 PHE have likely contributed to an increase in the demand for behavioral health services while also exacerbating existing barriers in beneficiaries' access to needed behavioral health services. In light of the feedback we have received and considering the increased needs for mental health services, we are proposing to create a new G code describing General BHI performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration. The proposed new code is GBHI1 (*Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.*) We are proposing to value this service under the proposed HCPCS code GBHI1 based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484 (*Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team*), because the services described by GBHI1 closely mirror those described by CPT code 99484. Therefore, we believe that this crosswalk is an appropriate valuation of the level, time, and intensity of the proposed service described by HCPCS code GBHI1. CPs are authorized under their statutory benefit category at section 1861(ii) of the Act to furnish ''qualified psychologist services'' to include ''such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.'' Additionally, the statutory benefit category for CSWs at Section 1861(hh)(2) of the Act defines ''clinical social worker services'' as ''services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.'' Based on the authorizations under the CP and CSW statutory benefit categories, CPs are authorized to furnish and bill for services that are provided by clinical staff incident to their professional services when the ''incident to'' requirements specified in § 410.26 of our regulations are met, and would be authorized to do the same when furnishing services described by proposed HCPCS code GBHI1, whereas CSWs would only be able to bill Medicare for services they furnish directly and personally. The proposed work value for HCPCS code GBHI1 is 0.61 (based on a direct crosswalk to CPT code 99484). We are seeking comment on whether this proposed value accurately reflects the resource costs involved in furnishing these models of care, or whether additional coding may be needed, for example, separate coding for CPs and CSWs. We are also seeking comment on the proposed requirements for billing GBHI1, including any applicable ''incident to'' requirements,

[43] *https://www.cms.gov/cms-behavioral-health-strategy.*

and the role and responsibilities of CSWs and CPs.

In the CY 2017 PFS final rule (81 FR 80239), we finalized the requirement of an initiating visit for the BHI codes for new patients or beneficiaries not seen within a year of commencement of BHI services. We stated that the initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the billing practitioner's professional services), ensure the billing practitioner assesses the beneficiary prior to initiating care management processes, and provide an opportunity to obtain beneficiary consent. We noted that the existing eligible initiating visit codes are not, in their entirety, within the scope of the CP's practice. Given that, we are proposing to allow a psychiatric diagnostic evaluation (CPT code 90791) to serve as the initiating visit for GBHI1. We welcome comment on whether we should consider additional codes to qualify as the initiating visit.

In the CY 2017 PFS final rule (81 FR 80235), we established that CCM and BHI services could be billed during the same month for the same beneficiary if all the requirements to bill each service are separately met. We are also proposing that HCPCS code GBHI1 could be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. The patient consent requirements would apply to each service independently.

In the CY 2017 PFS final rule (81 FR 80235), we established that the BHI services may be furnished incident to the billing professional's services under general supervision because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) to have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. We believe this is also the case for the service described by GBHI1. Therefore, consistent with other care management codes paid under the PFS, we are proposing to add HCPCS code GBHI1 to the list of designated care management services for which we allow general supervision.

(36) Request for Information: Medicare Part B Payment for Services Involving Community Health Workers (CHWs)

The American Public Health Association (APHA) defines a community health worker as a ''frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery.'' Community Health Workers are classified as a workforce category by the Department of Labor. The Community Health Worker Core Consensus Project (C3) lists the following ten roles of CHWs: [44]

- Cultural mediation among individuals, communities, and health and social service systems.
- Providing culturally appropriate health education and information.
- Care coordination, case management, and system navigation.
- Providing coaching and social support.
- Advocating for individuals and communities.
- Building individual and community capacity.
- Providing direct service.
- Implementing individual and community assessments.
- Conducting outreach.
- Participating in evaluation and research.

Findings from randomized controlled trials indicate that particular CHW interventions reduce chronic disease disparities in low income, racial and ethnic minority communities, such as type 2 diabetes, hypertension, HIV/AIDS, and obesity.[45] [46] [47] [48] [49] CMS is also interested in better addressing the social needs of beneficiaries; for example, in the FY 2023 IPPS/LTCH NPRM, CMS proposed new measures under the Hospital Inpatient Quality Reporting Program pertaining to assessing social determinants of health. The CHW skillset may position this workforce to address these social needs. In light of the significant benefits that services involving CHWs can potentially offer the health of Medicare beneficiaries, including a reduction in health disparities, CMS is interested in learning more about how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. For example, physicians and other eligible practitioners are able to report care management services and behavioral health integration services based on tasks personally provided by clinical staff under their supervision. Some of the elements of the comprehensive care plans referenced in the description of care management services include medication management, community/social services ordered, and coordination with other agencies, which are also some of the services personally provided by CHWs.

Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We are interested in learning whether and how CHWs, as auxiliary personnel of physicians and hospitals, may provide reasonable and necessary services to Medicare beneficiaries under the appropriate supervision of health care professionals that are responsible more broadly for medical care, including behavioral health care. We are also looking to understand whether and how services involving CHWs are accounted for under the existing CCM codes or other care management or behavioral health integration services, including whether the employment and supervision arrangements ordinarily adopted within the industry would meet the requirements that allow for billing by supervising professionals or providers, including RHCs and FQHCs. For example, do CHWs tend to be

[44] St John, J.A., Mayfield-Johnson, S.L., & Hernández-Gordon, W.D. (2021). Introduction: Why Community Health Workers (CHWs)? In *Promoting the Health of the Community* (pp. 3–10). Springer, Cham.

[45] Kangovi S, Mitra N, Grande D, Huo H, Smith RA, Long JA. Community Health Worker Support for Disadvantaged Patients With Multiple Chronic Diseases: A Randomized Clinical Trial. *Am J Public Health*. 2017;107(10):1660–1667. doi:10.2105/AJPH.2017.303985.

[46] Cooper L.A., Roter D.L., Carson K.A., et al. A randomized trial to improve patient-centered care and hypertension control in underserved primary care patients. J Gen Intern Med. 2011;26(11):1297–1304.

[47] Spencer MS, Rosland AM, Kieffer EC, Sinco BR, Valerio M, Palmisano G, et al. Effectiveness of a community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial. Am J Public Health. 2011 Dec;101(12):2253–60.

[48] Brown LD, Vasquez D, Lopez DI, Portillo EM. Addressing Hispanic Obesity Disparities Using a Community Health Worker Model Grounded in Motivational Interviewing. Am J Health Promot. 2022;36(2):259–268.

[49] Kenya, S., Jones, J., Arheart, K. *et al.* Using Community Health Workers to Improve Clinical Outcomes Among People Living with HIV: A Randomized Controlled Trial. *AIDS Behav* 17, 2927–2934 (2013).

employees of physicians or of the same entities that employ physicians? Are physicians or other medical professionals supervising their interaction with patients in a manner consistent with direct supervision—for example, immediate availability in the same location?

We note that CHWs are employed in a number of sectors, including local government, community-based organizations, and social services sectors. Therefore, the health care providers working with CHWs may have established nontraditional relationships with these organizations outside of the health sector. We are interested in learning how payments between health care provider organizations, and community-based organizations, local governments, and social service organizations, account for the costs of services provided by CHWs, and how health care provider organizations ensure that the funding amount is sufficient to cover the costs of the full range of CHW services. We are also seeking comment on whether and to what extent CHW services are provided in association with preventive services, including those covered by Medicare.

Physicians and certain other health care practitioners are authorized to bill Medicare for services furnished incident to their professional services by auxiliary personnel. Our regulation at § 410.26 requires that auxiliary personnel who perform services incident to the services of the billing physician or other practitioner must be acting under the supervision of the billing practitioner, and must meet any applicable requirements, including licensure, imposed by the State in which the services are furnished. We understand that there is wide variation in State standards for CHWs. In addition, the training that CHWs receive is typically provided by employers but varies widely in terms of its breadth and scope.[50] We are trying to understand how CHWs might also be recognized as auxiliary personnel in the Medicare context, and are therefore interested in learning how States may have determined whether and under what circumstances CHWs have the necessary qualifications to perform services that would improve the health of Medicare beneficiaries and others being treated by supervising professionals or providers.

[50] Fasting, D., Mayfield-Johnson, S.L., St. John, J.A., & Hernández-Gordon, W.D. (2021). In Promoting the Health of the Community (pp. 43–52). Springer, Cham.

(37) Proposed Recognition of the Nurse Portfolio Credentialing Commission (NPCC)

The Medicare program established qualifications under regulations at § 410.75 for NPs and, under 42 CFR 410.76 for clinical nurse specialists (CNS). Both the NP and CNS qualification regulations require that NPs and CNSs be certified as a NP or a CNS by a recognized national certifying body that has established standards for NPs and/or CNSs, and that a listed certifying body must be approved by the Secretary. An identical list of Medicare recognized and approved national certifying bodies for NPs and CNSs is included under Chapter 15, section 200 and 210 of the Medicare Benefit Policy Manual, pub. 100–02.

The organizations listed under program manual instructions as recognized national certifying bodies for NPs and CNSs are as follows:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

The Nurse Portfolio Credentialing Center (NPCC) has requested to have its organization added to the lists of recognized national certifying bodies for NPs and CNSs who specialize in clinical genetics/genomics and are awarded the Advanced Clinical Genomics Nurse (ACGN) credential. The NPCC's request to CMS describes the NPCC as a non-profit organization, established in 2018 by genetics/genomics nurse leaders as the only organization that now offers new credentials to advanced practice registered nurses (APRNs) who specialize in genetics/genomics, a nursing specialty recognized by the American Nurses Association.

Additionally, the NPCC's letter states that its organization evolved directly from the American Nurses Credentialing Center (a listed, CMS-recognized national certifying body) and the Genetic Nursing Credentialing Commission, which are the organizations that awarded new genetics/genomics nursing credentials from 2001 to 2018. However, as of 2019, the American Nurses Credentialing Center (ANCC) stopped offering new credentialing to genetics nurses and instead offers only renewal credentialing to nurses who specialize in genetics. Since 2019, the NPCC has awarded the ACGN credential to 32 APRNs from 17 States.

Now, with the NPCC being the only organization that offers new credentialing to nurses in genetics, the NPCC is concerned that the absence of its organization from the current list of recognized national certifying bodies appropriate for NPs and CNSs presents a barrier and a disadvantage for newly credentialed APRNs. Specifically, the NPCC is concerned that newly NPCC credentialed NPs and CNSs seeking enrollment under Medicare would be denied on the basis that they do not meet Medicare's certification requirement unless the NPCC is listed as a recognized national certifying body appropriate for NPs and CNSs who specialize in genetics/genomics. The website for the NPCC is available at *https://www.nurseportfolio.org.*

When considering previous requests to add other organizations to the list of recognized national certifying bodies for NPs and CNSs, we stated that it is not our intention to be overly restrictive in our program requirements and consequently prevent qualified NPs and CNSs who specialize in areas of medicine other than those certified by the ANCC from participating in the Medicare program as NPs or CNSs and from rendering care to patients in need of specialized services (see 71 FR 69707). Accordingly, we are proposing to add the NPCC organization to the list of recognized national certifying bodies in manual instructions for NPs at section 200 and CNSs at section 210 of the Medicare Benefit Policy Manual, pub. 100–02. We request public comments on this proposal.

(38) Request for Information: Medicare Potentially Underutilized Services

Medicare provides payment for many kinds of services that support beneficiaries in promoting health and well-being and that may also, in some cases, reduce unnecessary spending within the health care system by decreasing the need for more expensive kinds of care. Some examples of these services may include patient educational services, like Diabetes Self-Management Training or preventive services, like the Annual Wellness Visit.

We are seeking comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by

Medicare beneficiaries. We are also seeking comment regarding how we might best mitigate some of these obstacles, including for example, through examining conditions of payment or payment rates for these services or by prioritizing beneficiary and provider education investments.

''High value'' health services have been described as those ''services that provide the best possible health outcomes at the lowest possible cost.'' [51] The American College of Physicians states that high value services seek ''to improve health, avoid harms, and eliminate wasteful practices.'' [52] However, we believe that some high value Medicare services may be potentially underutilized by beneficiaries. In some cases, limited use of these kinds of services occurs disproportionately in underserved communities.

Disparities in health and healthcare persist despite decades of research and widespread efforts to improve health outcomes in the United States.[53] Certain populations, including groups experiencing racial disparity, people with disabilities, individuals dually eligible for Medicare and Medicaid, and those living in rural and underserved areas are more likely to experience challenges accessing healthcare services, lower quality of care, and below average health outcomes when compared to the general population.[54] [55] [56] Many known factors impede efficient and equitable healthcare, including workforce challenges, transportation issues, healthcare costs, language barriers, a lack of health literacy, and confusion about health insurance coverage and processes.[57] Additional factors include social determinants of health and community-level burdens that contribute to the exacerbation of health disparities. For example, disparities in cancer screening and treatment across racial and ethnic groups have been well documented. Research demonstrates that minority populations are less likely to receive cancer screening tests than their white counterparts and, consequently, are more likely to be diagnosed with late-stage cancer.[58] Additionally, racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests that would serve to confirm cancer diagnoses.[59] CMS is committed to building solutions that will help close gaps in healthcare quality, access, and outcomes.[60]

We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[61] Health equity as defined by CMS [62] means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. More information regarding CMS's Strategic Plan for health equity is available in the CMS Strategic Plan Pillar: Health Equity Fact Sheet: *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

In light of the concerns regarding the potential underutilization of high value health services, particularly among potentially underserved communities, we are committed to promoting these high value services within the Medicare program. In concert with the CMS strategy to advance health equity in addressing health disparities that underlie our health system, we seek to engage with interested parties and solicit comment regarding ways to identify and improve access to high value, potentially underutilized services by Medicare beneficiaries.

We are seeking comment on how to best define and identify high value, potentially underutilized health services. We are also looking to understand what existing services within current Medicare benefits may represent high value, potentially underutilized services, such as:

- Preventive Services;
- Annual Wellness Visits;
- Diabetes Management Training;
- Screening for Diabetes;
- Referral to appropriate education/prevention/training services
- Immunizations/vaccinations
- Cancer screenings
- Cardiac rehabilitation services
- Intensive Behavioral Therapy for obesity
- Opioid treatment programs
- Complex/Chronic Care Management
- Cognitive Assessment & Care
- Behavioral Health Integration Services

Other examples of Medicare preventive services are available at the following website: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html.*

We invite the public to submit information about specific obstacles to

[51] ''Michigan Program on Value Enhancement.'' Institute for Healthcare Policy & Innovation (28 Apr. 2022). *https://ihpi.umich.edu/featured-work/michigan-program-value-enhancement.*

[52] High value care. ACP. (n.d.). (May 9, 2022). *https://www.acponline.org/clinical-information/high-value-care.*

[53] Office of Minority Health. (2021, January, page 3). *Paving the Way to Equity: A Progress Report.* Centers for Medicaid and Medicare Services. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[54] Agency for Health Care Research and Quality (AHRQ). (2021, June). *2019 National Healthcare Quality and Disparities Report.* AHRQ. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr19/index.html.*

[55] Executive Order No. 13985, 86 FR 7009 (2021, January 20). *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.* For the purposes of this RFI, we are using the definitions of equity and underserved communities established in Executive Order 13985, ''The term 'equity' means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' The term ''underserved communities'' refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

[56] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human. Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based. Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[57] Lahr, M., Henning-Smith, C., Rahman, A., Hernandez, A. (2021, January). *Barriers to Health Care Access for Rural Medicare Beneficiaries: Recommendations from Rural Health Clinics.* University of Minnesota Rural Health Research Center. *https://rhrc.umn.edu/wp-content/uploads/2021/01/UMN-RHC-Access-to-Care-PB_1.20.pdf.*

[58] Agency for Healthcare Research and Quality [AHRQ], 2004; National Institutes of Health/National Cancer Institute [NIH/NCI], 2001). Racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests needed to confirm cancer diagnoses (Battaglia et al., 2007; Ries et al., 2003.

[59] Battaglia et al., 2007; Ries et al., 2003.

[60] Office of Minority Health. (2021, January). *Paving the Way to Equity: A Progress Report.* Centers for Medicaid and Medicare Services. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[61] *https://www.cms.gov/pillar/health-equity.*

[62] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

accessing these services and how specific potential policy, payment or procedural changes could reduce potential obstacles and facilitate better access to high value health services. Specifically, we are soliciting new and innovative ideas that may help broaden perspectives about potential solutions. Ideas may include, but are not limited to:

- Educational or marketing strategies (informed by beneficiary input) to promote awareness of available programs and resources that advance the utilization of ''high value'' services;
- Aligning of Medicare and other payer coding, payment and documentation requirements, and processes related to ''high value'' services;
- Recommendations from States and other interested parties regarding how to best raise awareness of underutilized services, with special consideration for the dual-eligible population;
- Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance the utilization of ''high value'' services; and
- New recommendations regarding when and how CMS issues regulations and policies related to ''high value'' services and how CMS can advance rules and policies for beneficiaries, clinicians, and providers.

We are interested in learning about how CMS might best promote high value care and health equity, address concerns regarding health disparities, and increase access to high value services, which could improve the health of Medicare beneficiaries. Comments received in response to this RFI may be used to identify potential opportunities for improvement to and refinement of existing Medicare FFS and MA programs.

(39) Change in Procedure Status for Family Psychotherapy

The CPT codes that describe family psychotherapy are payable under Medicare, but are currently assigned a restricted status indicator in the Medicare Physician Fee Schedule payment files. The codes describing family psychotherapy with the patient present are CPT code 90847 (Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes) and CPT code 90849 (Multiple-family group psychotherapy). We note that CPT code 90846 (Family psychotherapy (without the patient present), 50 minutes) describes family psychotherapy without the patient present. In past rulemaking, we have discussed that Medicare coverage is limited to items and services that are for the diagnosis and treatment of the individual beneficiary. For example, in the CY 2013 PFS final rule (77 FR 68979), we stated that Medicare does not pay for services that are furnished to parties other than the beneficiary and which Medicare does not cover, for example, communication with caregivers.

During the COVID–19 pandemic, the number of adults reporting adverse behavioral health conditions has increased sharply, with higher rates of depression, substance use, and self-reported suicidal thoughts observed in racial and ethnic minority groups.[63] We are seeking to ensure that appropriate care is furnished to Medicare beneficiaries and note that CPT codes 90847 and 90849 are payable under Medicare. Accordingly, we are proposing to update our payment files to remove the restricted (''R'') procedure status indicator for CPT codes 90847 and 90849 and assigning these codes an active (''A'') procedure status indicator.

We note that there are national coverage determinations (NCDs) addressing family psychotherapy described by CPT codes 90847 and 90849 describing the settings of care in which these services are covered, documentation requirements and other guidelines.[64] The Medicare National Coverage Determinations (NCD) Manual, Pub. 100–03, section 70.1, titled ''Consultations with a Beneficiary's Family and Associates'' states that ''family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition.'' [65] The change to the ''A'' status indicator for these subject CPT codes does not alter the policy under the applicable coverage determinations for these codes.

(40) Comment Solicitation on Intensive Outpatient Mental Health Treatment, Including Substance Use Disorder (SUD) Treatment, Furnished by Intensive Outpatient Programs (IOPs)

There are a range of services described by existing coding under the PFS that can be billed for treatment of mental health conditions, including SUDs, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, we have increased the coding and payment mechanisms for substance use treatment services paid under the PFS. For example, in the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD) (HCPCS codes G2086–G2088). In the CY 2021 PFS final rule, we finalized expanding the bundled payments described by HCPCS codes G2086–G2088 to be inclusive of all SUDs (85 FR 84642 through 84643).

Additionally, in the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing bundled payments for episodes of care for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). Medicare also covers services furnished by inpatient psychiatric facilities and partial hospitalization programs (PHP). PHP services can be furnished by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHPs are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in § 1861(ff) of the Social Security Act (the Act). According to the Medicare Benefit Policy Manual, Chapter 6, Section 70.3, the treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation. PHPs work best as part of a community continuum of mental health services which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support.

We understand that in some cases, people that do not require a level of care for mental health needs that meets the standards for PHP services, nonetheless require intensive services on an outpatient basis. We are interested in whether or not the current coding and payment mechanisms under the PFS adequately account for intensive outpatient services that are part of a continuum of care in the treatment. For example, according to SAMHSA's *Advisory on Clinical Issues in Intensive Outpatient Treatment for Substance Use Disorders,* IOP programs for substance use disorders (SUDs) offer services to clients seeking primary treatment; step-down care from inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. IOP treatment includes a prearranged schedule of core services for example,

[63] *https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm.*

[64] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57065&ver=10&keyword=&keywordType=starts&areaId=all&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=90847&hcpcsEndCode=90847&sortBy=title&bc=1.*

[65] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=16&ncdver=1.*

individual counseling, group therapy, family psychoeducation, and case management) for a minimum of 9 hours per week for adults or 6 hours per week for adolescents. The 2019 National Survey of Substance Abuse Treatment Services reports that 46 percent of SUD treatment facilities offer IOP treatment.[66]

We are seeking comment on whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or substance use disorder treatment, including and especially SUDs, for Medicare beneficiaries. We are particularly interested in the extent to which any potential gaps would best be addressed by the creation of new codes, revision of particular billing rules for some kinds of care in specific settings, or whether the valuation of particular codes (existing or new) needs to be addressed in order to better reflect the relative resource costs involved in furnishing intensive outpatient mental health services. We are also interested in additional, detailed information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform our ability to ensure that Medicare beneficiaries have access to this care.

(41) Comment Solicitation on Payment for Behavioral Health Services Under the PFS

As discussed throughout this proposed rule, CMS is committed to ensuring that beneficiaries have access to needed services for mental and behavioral health. Through the CMS Behavioral Health Strategy, CMS seeks to remove barriers to care and services, and to adopt a data-informed approach to evaluate our behavioral health programs and policies. CMS strives to support a person's whole emotional and mental well-being and promote person-centered behavioral health care.[67]

As part of our review of our payment policies and systems, we understand that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to practice expense (PE). In the CY 2018 PFS final rule (82 FR 52999), we discussed that some interested parties had suggested that for codes in which direct PE inputs for a service are very low, the methodology for allocating indirect PE does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. We stated that primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders, are among the services most affected by our methodology.

We are soliciting comment on how we can best ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS.

BILLING CODE 4120–01–P

[66] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep20-02-01-021.pdf.*

[67] *https://www.cms.gov/cms-behavioral-health-strategy.*

TABLE 12: CY 2022 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
157X1	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	NEW	8.00	7.05	Yes
15851	Removal of sutures or staples requiring anesthesia (ie, general anesthesia, moderate sedation)	0.86	1.10	1.10	No
158X1	Removal of sutures or staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00	No
158X2	Removal of sutures and staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00	No
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	22.09	22.09	20.42	No
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace	5.22	5.22	5.22	No
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	27.75	26.80	24.83	No
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment	8.16	7.96	7.30	No
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	27.13	-	27.13	No
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level	7.03	7.03	7.03	No
22870	Insertion of interlaminar/interspinous process stabilization/distraction device,	2.34	2.34	2.34	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	without open decompression or fusion, including image guidance when performed, lumbar; second level				
228XX	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	NEW	C	C	No
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment	17.48	17.13	17.13	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	19.60	19.60	19.60	No
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	2.80	-	2.80	No
338X3	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, unilateral	NEW	14.00	11.03	No
338X4	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, bilateral	NEW	18.00	14.50	No
338X5	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, unilateral	NEW	17.33	14.00	No
338X6	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, bilateral	NEW	20.00	16.50	No
338X7	Percutaneous pulmonary artery revascularization by stent placement, each additional vessel or separate lesion, normal or abnormal connections	NEW	7.27	5.53	No
368X1	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	NEW	7.50	7.20	No
368X2	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	NEW	9.60	9.30	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
37X01	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling	NEW	2.70	2.44	No
42975	Drug induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing, flexible, diagnostic	1.90	1.95	1.58	No
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	2.09	2.09	2.09	No
43X21	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon	NEW	3.11	3.11	No
43X22	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)	NEW	2.80	2.80	No
49436	Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter	2.72	-	2.72	No
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	6.27	5.96	No
49X02	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	9.00	8.46	No
49X03	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	NEW	10.80	10.26	No
49X04	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when	NEW	14.00	13.46	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated				
49X05	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	14.88	13.94	No
49X06	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	20.00	18.67	Yes
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	7.75	7.42	No
49X08	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	10.79	10.25	No
49X09	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	NEW	12.00	11.46	No
49X10	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	NEW	16.50	15.55	Yes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
49X11	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	16.97	16.03	Yes
49X12	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	24.00	22.67	Yes
49X13	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible	NEW	14.24	13.70	Yes
49X14	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated	NEW	18.00	17.06	Yes
49X15	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic)	NEW	5.00	2.61	No
50080	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (eg, stone[s] up to 2 cm in single location of kidney or renal pelvis, nonbranching stones)	15.74	13.50	12.11	No
50081	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (eg, stone[s] > 2 cm, branching stones, stones in multiple locations, ureter stones, complicated anatomy)	23.50	22.00	20.61	No
55821	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and	15.76	15.18	15.18	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	internal urethrotomy); suprapubic, subtotal, 1 or 2 stages				
55831	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal	17.19	15.60	15.60	No
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	26.80	22.46	22.46	No
558XX	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	NEW	19.53	19.53	No
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical	16.20	15.95	14.91	No
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	13.18	13.18	12.00	No
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar	3.15	4.00	3.86	No
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment	4.25	5.70	4.25	No
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment	3.19	5.00	3.78	No
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, including imaging guidance, when performed	1.35	1.50	1.35	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.48	1.80	1.65	No
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve, including imaging guidance, when performed	1.27	1.31	1.31	No
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, including imaging guidance, when performed	1.00	1.39	1.28	No
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.36	1.75	1.64	No
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, including imaging guidance, when performed	1.10	1.34	1.34	No
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement), including imaging guidance, when performed	1.41	1.68	1.68	No
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor	8.69	8.00	6.68	No
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex	9.77	9.03	9.03	No
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor	8.80	8.48	7.91	No
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex	9.77	9.46	9.46	No
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor	5.93	7.50	6.36	No
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within	7.13	7.38	7.38	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex				
69XX0	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	9.97	9.97	No
69XX1	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	10.25	10.25	No
69XX2	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	NEW	8.50	8.50	No
73580	Radiologic examination, knee, arthrography, radiological supervision and interpretation	0.54	0.59	0.59	No
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation	0.79	0.79	0.79	No
76881	Ultrasound, complete joint (ie, joint space and peri-articular soft-tissue structures), real-time with image documentation	0.63	0.90	0.54	Yes
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation	0.49	0.69	0.59	No
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation	0.67	0.67	0.67	No
76XX0	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-	NEW	1.21	0.99	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	time cine imaging with image documentation, per extremity				
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)	0.54	0.54	0.54	No
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.60	0.60	No
90460	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered	0.17	0.24	0.24	No
90461	90461 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered	0.15	0.18	0.18	No
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	0.17	0.17	0.17	No
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)	0.15	0.15	0.15	No
90473	Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)	0.17	0.17	0.17	No
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)	0.15	0.15	0.15	No
92065	Orthoptic training; performed by a physician or other qualified health care professional	0.37	0.71	0.71	No
920XX	Orthoptic training; under supervision of a physician or other qualified health care professional	NEW	0.00	0.00	No
92284	Diagnostic dark adaptation examination with interpretation and report	0.24	0.14	0.00	Yes
92287	Anterior segment imaging with interpretation and report; with fluorescein angiography	0.81	0.40	0.40	No
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning	C	-	0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	analysis with report, review and interpretation				
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	0.00	-	0.00	No
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	C	-	0.00	No
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	0.50	-	0.50	No
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	C	-	0.55	No
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	0.00	-	0.00	No
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	C	-	0.00	No
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	0.55	-	0.55	No
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization	1.11	1.11	1.00	No
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization	1.13	1.13	1.03	No
93565	Injection procedure during cardiac catheterization including imaging supervision,	0.86	0.86	0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	interpretation, and report; for selective left ventricular or left atrial angiography				
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography	0.86	0.86	0.50	No
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography	0.97	0.97	0.70	No
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for nonselective pulmonary arterial angiography (List separately in addition to code for primary procedure)	0.88	0.88	0.88	No
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	14.75	15.00	13.80	No
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	19.75	18.10	16.90	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia	5.50	7.00	5.50	No
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed	19.77	17.00	15.80	No
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	5.50	7.00	5.50	No
93XX0	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral	NEW	1.05	0.63	No
93XX1	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral	NEW	1.75	1.30	No
93XX2	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization	NEW	1.84	1.44	No
93XX3	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, during cardiac catheterization for congenital heart defects, each distinct vessel	NEW	1.92	1.92	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
959XX	Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral	NEW	0.25	0.18	No
96X70	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	NEW	0.43	N	No
96X71	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes	NEW	0.12	N	No
989X6	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days	NEW	C	C	No
99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	1.92	1.63	1.63	No
99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.	2.61	2.60	2.60	No
99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level	3.86	3.50	3.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.				
99231	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.	0.76	1.00	1.00	No
99232	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded	1.39	1.59	1.59	No
99233	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.	2.00	2.40	2.40	No
99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	2.56	2.00	2.00	No
99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.	3.24	3.24	3.24	No
99236	Hospital inpatient or observation care, for the evaluation and management of a patient	4.20	4.30	4.30	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.				
99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter	1.28	1.50	1.50	No
99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter	1.90	2.15	2.15	No
99242	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	I	1.08	I	No
99243	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	I	1.80	I	No
99244	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	I	2.69	I	No
99245	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.	I	3.75	I	No
99252	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code	I	1.50	I	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	selection, 35 minutes must be met or exceeded.				
99253	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	I	2.00	I	No
99254	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	I	2.72	I	No
99255	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 80 minutes must be met or exceeded.	I	3.86	I	No
99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional	0.48	0.25	0.25	No
99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making	0.93	0.93	0.93	No
99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making	1.60	1.60	1.60	No
99284	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making	2.74	2.60	2.74	No
99285	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making	4.00	4.00	4.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99304	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.	1.64	1.50	1.50	No
99305	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.	2.35	2.50	2.50	No
99306	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	3.06	3.50	3.50	No
99307	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.	0.76	0.70	0.70	No
99308	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	1.16	1.30	1.30	No
99309	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.55	1.92	1.92	No
99310	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and	2.35	2.80	2.80	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.				
99315	Nursing facility discharge day management; 30 minutes or less	1.28	1.50	1.50	No
99316	Nursing facility discharge day management; more than 30 minutes	1.90	2.50	2.50	No
99341	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	1.01	1.00	1.00	No
99342	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.52	1.65	1.65	No
99344	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	3.38	2.87	2.87	No
99345	Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.	4.09	3.88	3.88	No
99347	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	1.00	0.90	0.90	No
99348	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and	1.56	1.50	1.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.				
99349	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	2.33	2.44	2.44	No
99350	Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	3.28	3.60	3.60	No
99358	Prolonged evaluation and management service before and/or after direct patient care; first hour	2.10	1.80	I	No
99359	Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes	1.00	0.75	I	No
993X0	Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time	NEW	0.81	I	No
99415	Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour	0.00	0.00	0.00	No
99416	Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes	0.00	0.00	0.00	No
99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time	I	0.61	I	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination, Medical decision making of moderate or high complexity, Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity, Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]), Medication reconciliation and review for high-risk medications, Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s), Evaluation of safety (eg, home), including motor vehicle operation, Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks, Development, updating or revision, or review of an Advance Care Plan, Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 60 minutes of total time is spent on the date of the encounter.	3.80	3.50	3.84	No
GAUDX	Audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing or balance assessment unrelated to hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids; (service may be performed once every 12 months)	NEW	-	0.80	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
GBHI1	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.	NEW	-	0.61	No
GRTM1	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes of evaluation and management services	NEW	-	0.62	No
GRTM2	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver over a calendar month; each additional 20 minutes of evaluation and management services during the calendar month	NEW	-	0.61	No
GRTM3	Remote therapeutic monitoring treatment assessment services, 20 minutes personally furnished by qualified nonphysician health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month	NEW	-	0.62	No
GRTM4	Remote therapeutic monitoring treatment assessment services, 20 minutes personally furnished by qualified nonphysician health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month; each additional 20	NEW	-	0.61	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	minutes personally furnished by nonphysician qualified health care professional				
GXXX1	Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	-	0.61	No
GXXX2	Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	-	0.61	No
GXXX3	Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact	NEW	-	0.61	No
GYYY1	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician	NEW	-	1.45	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	or other qualified health care professional, per calendar month				
GYYY2	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month	NEW	-	0.50	No

TABLE 13: CY 2022 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
157X1	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	7	3	L1: Refined time to standard for this clinical labor task	-1.82
157X1	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	4	3	L1: Refined time to standard for this clinical labor task	-0.46
157X1	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms	5	3	L1: Refined time to standard for this clinical labor task	-0.91
157X1	Impl absrb msh/prsth dly cls	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	4	3	L1: Refined time to standard for this clinical labor task	-0.46
43X21	Egd flx trnsorl dplmnt balo	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and referral forms	5	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.91
43X21	Egd flx trnsorl dplmnt balo	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	15	10	G1: See preamble text	-2.28
43X22	Egd flx trnsorl rmvl balo	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	10	2	L1: Refined time to standard for this clinical labor task	-3.64

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49436	Embedded ip cath exit-site	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.37
49X01	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X01	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Conduct patient communications	6	3	L1: Refined time to standard for this clinical labor task	-1.37
49X01	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X01	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X01	Rpr aa hrn 1st < 3 cm rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X02	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X02	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this	-4.55

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								clinical labor task	
49X02	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X02	Rpr aa hrn 1st < 3 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X03	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X03	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X03	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X03	Rpr aa hrn 1st 3-10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X04	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49X04	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X04	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X04	Rpr aa hrn 1st 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X05	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X05	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X05	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X05	Rpr aa hrn 1st > 10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X06	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this	-5.92

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								clinical labor task	
49X06	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X06	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X06	Rpr aa hrn 1st > 10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X07	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X07	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X07	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X07	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Conduct patient communications	6	3	L1: Refined time to standard for this clinical labor task	-1.37
49X07	Rpr aa hrn rcr < 3 rdc	L037D	RN/LPN/MTA	F	Complete pre-	7	3	L1: Refined	-1.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					procedure phone calls and prescription			time to standard for this clinical labor task	
49X08	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X08	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X08	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X08	Rpr aa hrn rcr < 3 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X09	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X09	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X09	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical	-1.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								labor task	
49X09	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X10	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X10	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X10	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X10	Rpr aa hrn rcr 3-10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X11	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X11	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X11	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	20	10	L1: Refined time to	-4.55

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					(including test results)			standard for this clinical labor task	
49X11	Rpr aa hrn rcr > 10 rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X12	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X12	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X12	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X12	Rpr aa hrn rcr > 10 ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X13	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X13	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
49X13	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
49X13	Rpr parastomal hernia rdc	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X14	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L1: Refined time to standard for this clinical labor task	-1.82
49X14	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L1: Refined time to standard for this clinical labor task	-5.92
49X14	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L1: Refined time to standard for this clinical labor task	-1.37
49X14	Rpr parastomal hrna ncr/strn	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L1: Refined time to standard for this clinical labor task	-4.55
63020	Neck spine disk surgery	EQ168	light, exam	F		125	0	E10: Equipment removed; not typically used for this procedure	-0.41
63030	Low back disk surgery	EQ168	light, exam	F		125	0	E10: Equipment	-0.41

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								removed; not typically used for this procedure	
76881	Us xtr non-vasc complete	L026A	Medical/Technical Assistant	NF	Confirm availability of prior images/studies	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.62
76881	Us xtr non-vasc complete	L026A	Medical/Technical Assistant	NF	Review patient clinical extant information and questionnaire	1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.31
76881	Us xtr non-vasc complete	L026A	Medical/Technical Assistant	NF	Provide education/obtain consent	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.62
90460	Im admin 1st/only component	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
90460	Im admin 1st/only component	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-	-0.20

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								highly technical equipment	
90460	Im admin 1st/only component	L037D	RN/LPN/MTA	NF	Perform regulatory mandated quality assurance activity (pre-service)	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.46
90471	Immunization admin	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
90471	Immunization admin	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.20
90471	Immunization admin	L037D	RN/LPN/MTA	NF	Perform regulatory mandated quality assurance activity (pre-service)	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient	-0.46

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								for a particular service	
90472	Immunization admin each add	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
90472	Immunization admin each add	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.08
90472	Immunization admin each add	L037D	RN/LPN/MTA	NF	Perform regulatory mandated quality assurance activity (pre-service)	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.46
90473	Immune admin oral/nasal	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
90473	Immune admin oral/nasal	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		20	10	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.20
90473	Immune admin oral/nasal	L037D	RN/LPN/MTA	NF	Perform regulatory mandated quality assurance activity (pre-service)	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.46
90474	Immune admin oral/nasal addl	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
90474	Immune admin oral/nasal addl	EF049	refrigerator, vaccine medical grade, w-data logger sngl glass door	NF		11	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.08
90474	Immune admin	L037D	RN/LPN/MTA	NF	Perform regulatory mandated	1	0	G6: Indirect Practice	-0.46

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	oral/nasal addl				quality assurance activity (pre-service)			Expense input and/or not individually allocable to a particular patient for a particular service	
92284	Dx dark adaptation exam i&r	EF030	table, motorized (for instruments-equipment)	NF		24	15	G1: See preamble text	-0.02
92284	Dx dark adaptation exam i&r	EQ165	lens set, trial, full diameter, w-frame	NF		24	15	G1: See preamble text	-0.02
99341	Home/res vst new sf mdm 15	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80
99342	Home/res vst new low mdm 30	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80
99344	Home/res vst new mod mdm 60	SJ053	swab-pad, alcohol	NF		2	0	G1: See preamble text	-0.08
99344	Home/res vst new mod mdm 60	SJ061	tongue depressor	NF		1	0	G1: See preamble text	-0.03
99344	Home/res vst new mod mdm 60	SK062	patient education booklet	NF		1	0	G1: See preamble text	-2.80

TABLE 14: CY 2022 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
43X22	Egd flx trnsorl rmvl balo	EQ235	suction machine (Gomco)	NF		53	45	E15: Refined equipment time to conform to changes in clinical labor time	-0.07
43X22	Egd flx trnsorl rmvl balo	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		53	45	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
43X22	Egd flx trnsorl rmvl balo	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	NF		80	72	E15: Refined equipment time to conform to changes in clinical labor time	-1.58
49436	Embedded ip cath exit-site	EF014	light, surgical	NF		70	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
49436	Embedded ip cath exit-site	EF015	mayo stand	NF		43	40	E15: Refined equipment time to conform to changes in clinical labor time	0.00
49436	Embedded ip cath exit-site	EF031	table, power	NF		70	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
49436	Embedded ip cath exit-site	EQ137	instrument pack, basic ($500-$1499)	NF		49	46	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

TABLE 15: CY 2022 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
88108, 88112, 88120, 88121, 88173, 88182, 88184, 88185	centrifuge tube	SL024	$0.08	$0.26	225%	1	2,631,215
88120, 88121, 88366, 88374, 88377	ThermoBrite	EP088	$4,625.07	$5,250.16	14%	3	259,145
88182, 88184, 88185	flow cytometer	EP014	$192,000.00	$205,774.80	7%	1	1,991,567
88184, 88185	lysing reagent (FACS)	SL089	$3.645	$1.60	-56%	1	1,990,922
88302, 88304, 88305, 88307, 88309, 88355, 88362, G0416	embedding paraffin	SL061	$5.30	$9.38	77%	1	12,572,274
88302, 88304, 88305, 88307, 88309, G0416	Clarifier	SL469	$0.005	$0.007	40%	1	12,572,163
88364, 88365, 88367, 88368, 88369, 88373	Universal Detection Kit	SA117	$4.00	$6.05	51%	1	70,414
56 codes	towel, paper (Bounty) (per sheet)	SK082	$0.007	$0.015	114%	1	-
58 codes	cover slip, glass	SL030	$0.079	$0.114	44%	1	-
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$200.15	$245.69	23%	19	428,031

TABLE 16: CY 2022 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
368X1	Ellipsys Vascular Access Catheter	SD351	6,000.00	1	91
368X1	Ellipsys EndoAVF generator	EQ404	3,000.00	1	91
368X2	Wavelinq EndoAVF catheters	SD350	7,000.00	1	73
368X2	Wavelinq EndoAVF generator	EQ403	18,580.00	1	73
37X01	VivAer Stylus	SD352	1,950.00	7	50
37X01	Aerin Console Set	EQ405	4,995.00	4	50
43X21	ORBERA Intragastric Balloon System (balloon, placement catheter and connection tube with 3-way valve and saline bag spike)	SD348	1,850.00	8	1,075
43X22	Needle aspirator and grasper	SD349	94.00	7	9
49436	dressing, 1in, 7mm hole, w-CHG (eg, Biopatch)	SG099	9.37	1	115
49436	peritoneal dialysis catheter locking titanium adapter	SD353	169.74	1	115
49436	peritoneal dialysis catheter transfer set	SD354	47.17	1	115
49436	peritoneal dialysis catheter mini-cap for transfer set	SD355	0.35	1	115
92065, 920XX	Pro Vision Therapy Starter System Model VTSSP	ER122	2,229.95	1	26,730
92065, 920XX	Sanet Vision Integrator display/software	ER123	8,245.00	1	26,730
92284	Dark Adaptometer	ER124	29,925.00	1	40,710
959XX	Pupillometer Kit	ER125	8,995.00	1	2,110
96X70	2 inch 3 ring binder w/set of 8 dividers	SK134	7.91	1	-

TABLE 17: CY 2022 No PE Refinements

HCPCS	Description
15851	Removal sutr/staple req anes
158X1	Removal sutr/stapl xreq anes
158X2	Removal sutr&stapl xreq anes
22630	Lumbar spine fusion
22632	Spine fusion extra segment
22633	Lumbar spine fusion combined
22634	Spine fusion extra segment
22857	Tot disc arthrp 1ntrspc lmbr
22869	Insj stablj dev w/o dcmprn
22870	Insj stablj dev w/o dcmprn
27446	Revision of knee joint
27447	Total knee arthroplasty
30468	Rpr nsl vlv collapse w/implt
368X1	Prq av fstl crtj uxtr 1 acs
368X2	Prq av fstl crt uxtr sep acs
37X01	Rpr nsl vlv collapse w/rmdlg
42975	Dise eval slp do brth flx dx
43235	Egd diagnostic brush wash
50080	Perq nl/pl lithotrp smpl<2cm
50081	Perq nl/pl lithotrp cplx>2cm
55821	Removal of prostate
55831	Removal of prostate
55866	Laparo radical prostatectomy
558XX	Laps surg prst8ect smpl stot
63035	Spinal disk surgery add-on
63052	Lam facetc&frmt arthrd lum 1
63053	Lam factc&frmt arthrd lum ea
64415	Njx aa&/strd brch plxs img
64416	Njx aa&/strd brch pl nfs img
64417	Njx aa&/strd ax nerve img
64445	Njx aa&/strd sciatic nrv img
64446	Njx aa&/strd sc nrv nfs img
64447	Njx aa&/strd femoral nrv img
64448	Njx aa&/strd fem nrv nfs img
69714	Impltj oi implt skl perq esp
69716	Impl oi implt sk tc esp<100
69717	Rplcmt oi implt skl prq esp
69719	Rplcm oi implt sk tc esp<100
69726	Rmv ntr oi implt skl prq esp
69727	Rmv ntr oi imp sk tc esp<100
69XX0	Impl oi implt sk tc esp≥100
69XX1	Rplcm oi implt sk tc esp≥100
69XX2	Rmv ntr oi imp sk tc esp≥100
73580	Contrast x-ray of knee joint
76377	3d render w/intrp postproces
76882	Us lmtd jt/fcl evl nvasc xtr
76942	Echo guide for biopsy
76XX0	Us nrv&acc strux 1xtr compre
77002	Needle localization by xray
77003	Fluoroguidc for spinc injcct
90461	Im admin each addl component
92065	Orthop traing pfrmd phys/qhp
920XX	Orthop traing supvj phys/qhp

HCPCS	Description
92287	Internal eye photography
959XX	Quan puplmtry phy/qhp uni/bi
96X70	Mlt fam grp bhv train 1st 60
96X71	Mlt fam grp bhv train ea add
99221	1st hosp ip/obs sf/low 40
99222	1st hosp ip/obs moderate 55
99223	1st hosp ip/obs high 75
99231	Sbsq hosp ip/obs sf/low 25
99232	Sbsq hosp ip/obs moderate 35
99233	Sbsq hosp ip/obs high 50
99234	Hosp ip/obs sm dt sf/low 45
99235	Hosp ip/obs same date mod 70
99236	Hosp ip/obs same date hi 85
99238	Hosp ip/obs dschrg mgmt 30/<
99239	Hosp ip/obs dschrg mgmt >30
99242	Off/op consltj new/est sf 20
99243	Off/op cnsltj new/est low 30
99244	Off/op cnsltj new/est mod 40
99245	Off/op consltj new/est hi 55
99304	1st nf care sf/low mdm 25
99305	1st nf care moderate mdm 35
99306	1st nf care high mdm 45
99307	Sbsq nf care sf mdm 10
99308	Sbsq nf care low mdm 15
99309	Sbsq nf care moderate mdm 30
99310	Sbsq nf care high mdm 45
99315	Nursing fac discharge day
99316	Nursing fac discharge day
99345	Home/res vst new high mdm 75
99347	Home/res vst est sf mdm 20
99348	Home/res vst est low mdm 30
99349	Home/res vst est mod mdm 40
99350	Home/res vst est high mdm 60
99358	Prolong service w/o contact
99359	Prolong serv w/o contact add
993X0	Prolng ip/obs e/m ea 15 min
99415	Prolong clincl staff svc
99416	Prolong clincl staff svc add
99417	Prolng op e/m each 15 min
99483	Assmt & care pln pt cog imp

BILLING CODE 4120–01–C

F. Evaluation and Management (E/M) Visits

1. Background

Over the past several years, CMS has engaged in a multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits, so that they better reflect the current practice of medicine, are less administratively complex, and are paid more accurately under the PFS. This work is critical to help reduce practitioner burnout in general, especially in light of the COVID–19 pandemic. In a step-wise approach, the AMA CPT Editorial Panel revised the office/outpatient (O/O) E/M visit code family first. Effective January 1, 2021, the CPT Editorial Panel redefined the O/O E/M visits, such that visit level is selected based on the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM) as redefined in the CPT E/M Guidelines. Additionally, effective January 1, 2021, history of present illness (History) and a physical exam are no longer required elements of these services or used to select the O/O E/M visit level. (See 85 FR 84549). Also, effective January 1, 2021, the CPT Editorial Panel revised the O/O E/M visit descriptor times and the CPT E/M Guidelines.

We generally adopted these revised codes and changes in CPT code selection and documentation guidance for payment purposes under the PFS effective January 1, 2021 (84 FR 62844 through 62859). While we accepted the revised CPT codes and approach for the O/O E/M visits, we did not accept the revisions for prolonged O/O services, because we were concerned that they could have resulted in overpayment, were administratively complex, and would have impacted our ability to tell how much total time was spent with the

patient (see 84 FR 62849 through 62850). We created G2212 for reporting of prolonged O/O E/M services. Finally, the AMA RUC resurveyed the O/O E/M visits, and we generally accepted the RUC recommendations, which reflected increased service times (84 FR 62851 through 62854). This resulted in increased values for the O/O E/M codes beginning in CY 2021. Also, we created add-on code G2211 (*office/outpatient E/M visit complexity*) that can be reported in conjunction with O/O E/M visits to better account for resources associated with primary care or care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition(s). (84 FR 62854 through 62856). The Consolidated Appropriations Act, 2021 imposed a moratorium on Medicare payment for these services by prohibiting CMS from making payment under the physician fee schedule for HCPCS code G2211 before January 1, 2024. See our fact sheet available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet [68] (*cms.gov*).

For CY 2023, the AMA CPT Editorial Panel has revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. Hereafter in this proposed rule, we refer to these other E/M visit code families as ''Other E/M'' visits or CPT codes, as relevant. Effective January 1, 2023, the CPT Editorial Panel has redefined the Other E/M visits so that they parallel the O/O E/M visits, where visit level will be selected based on the amount of practitioner time spent with the patient or the level of MDM as redefined in the CPT E/M Guidelines. History and physical exam will only be considered when and to the extent that they are medically appropriate, and will no longer impact the Other E/M visit level. The CPT Editorial Panel also revised the service times within the descriptors, the associated prolonged service codes, and the CPT E/M Guidelines for the Other E/M CPT codes. We note that the CPT Editorial Panel also consolidated a considerable number of the Other E/M CPT codes, with inpatient and observation visits being combined into a single code set, and home and domiciliary visits being combined into a single code set. Currently there are approximately 75 Other E/M CPT codes, and in 2023 there will be approximately 50 Other E/M CPT codes. The CPT Editorial Panel created one new CPT code for prolonged inpatient services by physicians and other qualified healthcare professionals on the date of the E/M visit. Finally, the RUC has resurveyed the Other E/M visits and associated prolonged service codes, and provided revaluation recommendations to CMS.

In total, E/M visits comprise approximately 40 percent of all allowed charges under the PFS. The subset of Other E/M visits comprises approximately 20 percent of all allowed charges. Accordingly, our final policies for the Other E/M visits will have a significant impact on relative resource valuation under the PFS, which could potentially impact patient care more broadly. In this section of our proposed rule, we propose policies addressing coding and revaluation of Other E/M visits beginning for CY 2023. We also propose a technical correction to the placement of our regulation text for split (or shared) visits, and, as we further consider feedback from interested parties, we propose to delay implementation of our policy to define the substantive portion of a split (or shared) visit at § 415.140 based on the amount of time spent by the billing practitioner until January 1, 2024. Finally, we provide clarification and propose a technical correction regarding how time is reported for split (or shared) critical care visits.

2. Overview of Policy Proposals

We are proposing to generally adopt the revised CPT E/M Guidelines for Other E/M visits, which are available online at *www.ama-assn.org/cpt-evaluation-management.* We propose to adopt the general CPT framework for Other E/M visits, such that practitioner time or MDM would be used to select the E/M visit level. This includes the listing of qualifying activities by the physician or NPP that count toward the time spent when time is used required to select the visit level. History and physical exam would be considered, as medically appropriate, and would no longer be used to select visit level. We would not adopt the general CPT rule [69] where a billable unit of time is considered to have been attained when the midpoint is passed (for example, we would not consider a service with a time descriptor of 30 minutes to have been satisfied if only 15 minutes of time had been spent furnishing that service). We similarly interpreted this rule for O/O E/M visits, when time is used to select visit level. For example, we required the full time within the CPT code descriptors to be met in order to select an O/O E/M visit level using time, rather than half of the descriptor time (84 FR 62848 through 62851). Also, we do not interpret the CPT E/M Guidelines as adopting this general CPT rule regarding the midpoint of time.

We are proposing to adopt the revised CPT codes and descriptors for Other E/M visits, except where specified otherwise. Under our proposed policies, we would adopt the new CPT codes and descriptors for Other E/M visits except for prolonged services, for which we propose Medicare-specific coding. For administrative simplicity and payment accuracy purposes, and to enable us to determine how much time was spent with the patient using claims data, prolonged Other E/M services would be reported under one of three proposed G codes (one for each family for which prolonged services apply, namely inpatient/observation visits, nursing facility visits, and home or residence visits). This would be consistent with our previously finalized approach to prolonged O/O E/M services.

We are proposing to adopt the CPT E/M Guidelines regarding MDM for E/M services. The CPT Editorial Panel revised the CPT E/M guidelines for levels of MDM, and we are proposing to adopt them as revised.

In addition, as we note in the Medicare Claims Processing Manual ((pub 100–04) chapter 26, section 10.8), our longstanding taxonomy for PFS services will continue to apply, where, for payment purposes, physicians and NPPs are not classified as having the same specialty, and the PFS does not recognize subspecialties. However, we are continuing to consider whether we could better align this payment taxonomy with clinical practice, where we might consider NPPs as working in the same specialty as the physicians with whom they work, and/or recognize subspecialties.

Regarding valuation of the Other E/M CPT codes, the RUC recommended direct work RVU comparisons for many Other E/M CPT codes to those currently assigned to O/O E/M CPT codes. In some cases, there were assumptions that patient needs were inherently more complex or work was more intense for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) when compared to the office settings. This direct comparison to the O/O visit codes may not be appropriate or accurate, given that

[68] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

[69] Introduction to 2022 CPT Codebook, p.xviii.

practitioners furnishing visits in the office setting face particular uncertainties in their estimates of illness and treatment courses, and the office settings have fewer resources close at hand. For example, compared to fully-staffed institutional settings, office settings generally have smaller, ancillary staff complements (such as pharmacists, registered nurses, social workers, and other paraprofessionals) who provide specialized advice and services, spend time coordinating with other practitioners for review and evaluation of medical records and test results, educate patients, manage medications, and assess and help address social determinants of health. Additionally, those practicing in institutional settings generally have ready availability of diagnostic equipment (for example, imaging and other advanced services), allowing for more immediate access to clinical information and reducing the amount of time needed to manage a given case. This access is critical for positive health outcomes, to treat or prevent acute exacerbations of chronic conditions and timely manage patients to prevent deterioration and improve outcomes. The challenge of coordinating and gathering these types of care and information in the office setting may add additional time and complexity to the case management. Further, some of the Other E/M CPT code families are being merged into lower complexity settings, such as CPT codes for observation services migrating into the inpatient visit CPT codes.

The values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with a policy that would have provided separate payment for the new add-on code G2211. This add-on code describes the complexity inherent to E/M visits associated with primary care and other similar types of care (specifically, E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition, regardless of the specialty of the billing professional) (see 85 FR 84569 through 84572). Section 113 of the Consolidated Appropriations Act, 2021 delayed Medicare payment for G2211 until at least January 1, 2024 (see the following Fact Sheet available on our website at Physician Fee Schedule [70] (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet (cms.gov). To the extent we are proposing to adopt the RUC-recommended values for Other E/M visits beginning for CY 2023, we do not agree with the RUC that the current visit payment structure among and between care settings fully accounts for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values, since separate payment is not yet made for G2211.

3. Hospital Inpatient or Observation Care (CPT Codes 99218–99236)

a. Coding Changes and Visit Selection for Hospital Inpatient or Observation Care Services

The CPT Editorial Panel deleted seven observation care codes and revised nine codes effective January 1, 2023, to create a single set of codes for inpatient and observation care. (Note that the CPT Editorial Panel also made changes to codes for inpatient and observation discharge, which will be discussed in section II.F.4. of this proposed rule.) The CPT Editorial Panel also changed the code descriptors to allow level of service to be based on total time or MDM, as well as updating documentation requirements.

The CPT Editorial Panel deleted the six codes that were used to report observation care visits: three initial observation care codes, CPT codes 99218 *(Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; a detailed or comprehensive examination; and medical decision making that is straightforward or of low complexity). Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit),* 99219 *(Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity). Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit),* and 99220 *(Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital ''observation status'' are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit);* and three subsequent observation care codes, CPT codes 99224 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; problem focused examination; medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit*), 99225 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit*), and 99226 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of*

[70] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

these 3 key components: A detailed interval history; a detailed examination; medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit).

The CPT Editorial Panel also revised the six hospital inpatient care codes. The revisions allow these codes to be reported for hospital inpatient or observation care services and allow the codes to be selected by the billing practitioner based on either MDM or time. In addition, the CPT Editorial Panel changed the name of the ''Hospital Inpatient Care'' code family to ''Hospital and Observation Care,'' and the new code family includes three initial hospital or observation care codes: CPT codes 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded*), 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded*), and *99223 (Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded);* and three subsequent inpatient or observation care codes, CPT codes 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded*), 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded*), and 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded*).

The CPT Editorial Panel also revised the three codes under ''Observation or Inpatient Care Services (including Admission and Discharge)'' (frequently referred to as ''same-day discharge'' codes). Billing practitioners could already use these codes to bill for patients in inpatient or observation status, but the CPT Editorial Panel revised the codes to allow the billing practitioner to select the code level based either on MDM or time. The same-day discharge codes were renamed as ''Hospital Inpatient or Observation Care (Admission and Discharge)'': CPT codes 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded),* 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded*), and 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded*).

We propose to adopt the revised CPT codes 99221 through 99223 and 99231 through 99236. We highlight that the CPT code descriptors specify that, when selecting the code level based on time, the indicated increment of time must be ''met or exceeded.'' We propose that, when a physician or practitioner selects CPT codes 99221 through 99223 and 99231 through 99236 based on time, the number of minutes specified in the descriptor for the relevant CPT code must be ''met or exceeded.'' We note that we are not proposing to adopt the CPT Codebook instructions regarding the application of prolonged codes to CPT codes 99223, 99233, and 99236; refer to additional discussion under ''Prolonged Codes for Hospital Inpatient or Observation Care'' in this section.

We also note that the descriptors for CPT codes 99221 through 99223 and 99231 through 99236 specify that the time counted toward the code is ''per day.'' We propose to adopt the 2023 CPT Codebook instruction that ''per day,'' also referred to as ''date of encounter,'' means the ''calendar date.'' (2023 CPT Codebook citation forthcoming.) We also propose to adopt the 2023 CPT Codebook instruction that when using MDM or time for code selection, a continuous service that spans the transition of 2 calendar dates is a single service and is reported on one date, which is the date the encounter begins. If the service is continuous before and through midnight, all the time may be applied to the reported date of the service, that is, the calendar date the encounter began. (2023 CPT Codebook citation forthcoming.) We note that nothing in this proposal is intended to conflict with our proposed retention of the ''8 to 24 hour rule,'' discussed in the next section.

Finally, we propose to retain our policy that a billing practitioner shall bill only one of the hospital inpatient or observation care codes for an initial visit, a subsequent visit, or inpatient or observation care (including admission and discharge), as appropriate, once per calendar date. We propose that the practitioner would select a code that reflects all of the practitioner's services provided during the date of the service, as provided in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.9.B. We discuss additional policies relating to a single billing practitioner providing services to a single beneficiary on the same day in section II.F.3.d. of this proposed rule.

b. Proposed ''8 to 24 Hour Rule'' for Hospital Inpatient or Observation Care

We propose to retain what is known as the ''8 to 24-hour rule'' regarding payment of discharge CPT codes 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less*) and *99239* (*more than 30 minutes*). (CPT codes 99238 and 99239 are discussed in further detail in section

II.F.4. of this proposed rule.) The ''8 to 24 hour rule'' is described in further detail in the Medicare Claims Processing Manual (IOM 100–04, Chapter 12, 30.6.8.B and 30.6.9.1.C.). As we discussed in the CY 2001 PFS final rule (65 FR 65376), the ''8 to 24 hour rule'' was designed to avoid unintended incentives to keep a patient in the hospital past midnight during a stay lasting less than 24 hours. When this policy was memorialized in the CY 2001 PFS final rule, it was applied to both the initial inpatient hospital care codes (CPT codes 99221 through 99223) and the initial observation care codes (CPT codes 99218 through 99220) which CPT has deleted for 2023. The policy we propose to retain is as follows:

- If the beneficiary receives less than 8 hours of hospital inpatient or observation services, the practitioner may not bill for hospital inpatient and observation discharge day management services (to be described by CPT codes 99238 and 99239). If a patient receives less than 8 hours of hospital inpatient or observation services, we propose that the practitioner would bill only initial inpatient or observation care (described by CPT codes 99221, 99222, or 99223, as appropriate).
- If a beneficiary receives hospital inpatient or observation services for a minimum of 8 hours but less than 24 hours, we propose that the practitioner would bill CPT codes 99234, 99235, or 99236, as appropriate. (These codes, commonly referred to as ''same-day discharge'' codes, describe hospital inpatient or observation care that includes both admission and discharge as part of a single service.)
- If a beneficiary is admitted for hospital inpatient or observation care and is then discharged after more than 24 hours, we propose that the practitioner would bill an initial hospital inpatient or observation care code (CPT codes 99221 through 99223) for the date of admission, and a hospital discharge day management service (CPT code 99238 or 99239) on the date of discharge.

We believe it remains necessary to retain our 8 to 24 hour policy to avoid overpayments or create incentives to unnecessarily extend beneficiaries' hospital stays past midnight. Hospital inpatient and observation care codes (CPT codes 99221 through 99223 and 99234 through 99239) are billed ''per day,'' and have been valued to account for all services a practitioner furnishes during the day-long billing period. In an environment such as a hospital, where admissions can occur 24 hours a day, relying solely on the calendar date of an admission or observation stay, to determine a billing day can be misleading, which is why we propose to retain the existing 8 to 24 hour policy.

For example, Patient A was admitted by Physician A at 11:00 p.m. on April 1st and discharged at 6:00 a.m. on April 2nd. Patient B was admitted by Physician B at 8:00 a.m. on April 1st and discharged at 9:00 p.m. on April 2nd. Both Patient A and Patient B were in the hospital on the same two calendar dates (April 1 and April 2), but Patient A's stay was only 7 hours and Patient B's stay was 25 hours. Allowing both Physician A and Physician B to bill similarly (that is, both an initial hospital visit for April 1 and a discharge day management code for April 2nd) would be inappropriate. Both initial hospital visits and discharge day management codes are billed ''per day'' (and are valued as being ''per day''). Allowing a physician to bill for two ''per day'' services, delivered to the same patient in the same setting in less than an 8-hour period results in duplicative payment. This also may create an incentive for patients to be kept in the hospital past midnight, just to get to a second calendar date in which a practitioner is able to bill for two services rather than one.

We also note that CPT codes 99234, 99235, and 99236 are valued to include physician time spent admitting, caring for, and discharging the patient. These codes are billed for stays longer than 8 hours to acknowledge the increased resources inherent to caring for a patient during a longer hospital stay.

For another illustration of why relying solely on the calendar date of admission to determine the billing date is misguided, Patient A is admitted at 11 a.m. on April 1st and discharged at 11 p.m. on April 1st. Patient B is admitted at 11 p.m. on April 1st and discharged at 11 a.m. on April 2nd. Both patients are in the hospital for 12 hours. The practitioner treating Patient A would bill for a same-day discharge service, CPT code 99234 through 99236. It would not be appropriate to allow the practitioner treating Patient B to bill separately for an initial visit (CPT codes 99221 through 99223) and a separate discharge day management service (CPT codes 99238 or 99239) simply because Patient B's visit happened to span two calendar days and Patient A's did not. Under the proposed 8 to 24-hour rule, the practitioner treating Patient B would also bill for a same-day discharge service, CPT code 99234 through 99236.

We believe that by tying billing to the length of hospital stay rather than the calendar date, the 8 to 24-hour rule avoids confusion and the potential for overpayment of multiple E/M visits improperly billed for the same period of service.

c. Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit

According to the 2023 CPT Codebook (citation forthcoming), an ''initial'' service may be reported when ''the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay. When advanced practice nurses and physician assistants are working with physicians they are in the exact same specialty and subspecialty as the physician.'' The revised CPT codes 99231 through 99233 describe subsequent hospital inpatient or observation care services similarly. According to the 2023 CPT Codebook (citation forthcoming), a ''subsequent'' service is reported when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay.

As we do not recognize subspecialties, we propose slightly amended definitions of ''initial'' and ''subsequent'' service:

- An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.

These are the same definitions that we propose for ''initial'' and ''subsequent'' in the context of nursing facility visits below. We are also proposing that for both initial and subsequent visits, when advanced practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician (see section II.F.2. of this proposed rule).

d. Transitions Between Settings of Care and Multiple Same-Day Visits for Hospital Patients Furnished by a Single Practitioner

We propose to retain our current policy that for the purposes of reporting an initial hospital inpatient or observation care service, a transition from observation status to inpatient status does not constitute a new stay. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.8.D.) For instance, if a practitioner places a beneficiary in observation status on one date of service (and bills an initial observation visit to be described under CPT code 99221 through 99223), and then determines later in the stay that the beneficiary should be admitted to the hospital as an inpatient, the practitioner would not bill a second initial visit for the hospital inpatient stay. Rather, the practitioner would bill the work done on the inpatient admission day as a subsequent visit (CPT codes 99231, 99232, or 99233). This policy aligns with language in the 2023 CPT Codebook instructions (citation forthcoming.)

We also propose to retain our policy that if a patient is seen in a physician's office on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same physician, both visits are payable to that physician, even if less than 24 hours has elapsed between the visit and the hospital inpatient or observation care. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.9.1.B.) We also propose, however, to retain our current policy that when a patient is admitted to outpatient observation or as a hospital inpatient via another site of service (such as, hospital ED, physician's office, nursing facility), all services provided by the physician in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed *on the same date as the admission.* (Refer to the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.9.1.A.) This policy differs somewhat from the instructions provided in the 2023 CPT Codebook (citation forthcoming.)

We believe it is important to retain both policies, as they promote appropriate payment in situations in which the beneficiary visits the practitioner in a non-hospital setting before the practitioner determines that hospital admission is necessary. The codes for initial hospital inpatient or observation visits (CPT codes 99221 through 99223) are billed ''per day'' and include all work furnished by the practitioner on the day of admission. The initial hospital inpatient and observation care codes do not include work furnished by the practitioner prior to the date of admission. Thus, under our proposal, for example, if a practitioner sees a beneficiary in an office setting at 5 p.m. on April 1st and the practitioner then oversees the beneficiary's admission to the hospital at 7 a.m. on April 2nd, these would be separately billable payments because initial hospital inpatient or observation care codes (CPT code 99221 through 99223) billed for April 2nd would not retroactively cover the work furnished on April 1st. However, if the practitioner sees the beneficiary in the office setting at 7 a.m. on April 1st and then oversees the beneficiary's admission at 9 p.m. on April 1st, all time the practitioner spent furnishing services to that beneficiary would be reportable under the initial hospital inpatient or observation care code (CPT code 99221 through 99223).

We also propose to retain our current billing policy in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.1.A. that a physician may bill only for an initial hospital or observation care service if the physician sees a patient in the ED and decides to either place the patient in observation status or admit the patient as a hospital inpatient. For discussion of additional policy proposals regarding patients seen in both the ED and the hospital, refer to the next section, ''Emergency Department Services.''

We propose to preserve our current billing policies for patients in swing beds, which are as follows: If the inpatient care is being billed by the hospital as inpatient hospital care, the hospital care codes (CPT codes 99221 through 99223 and 99231 through 99239) apply. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.9.D.) If the inpatient care is being billed by the hospital as nursing facility care, then the nursing facility codes (CPT codes 99304 through 99316) apply. Refer to the section below on Nursing Facility Care Services for additional discussion of billing hospital inpatient or observation care and nursing facility care.

e. Impact of Changes to Hospital Inpatient or Observation Codes on Billing and Claims Processing Policies

We propose that starting in CY 2023, hospital inpatient and observation care by physicians will be billed using the same CPT codes, CPT codes 99221 through 99223, 99231 through 99233, and 99238 and 99239. (We note that currently, both hospital inpatient and observation care are already billed under CPT codes 99234 through 99236 for same-day discharge.) Therefore, though the current observation care codes (CPT codes 99218 through 99220 and 99224 through 99226) are being deleted, practitioners will still be able to furnish and bill for observation services. We solicit feedback from the public on potential challenges to billing or claims processing policies for hospital inpatient or observation care as reflected in the Medicare Claims Processing Manual (Medicare Claims Processing Manual, IOM 100–04, Chapter 12), including possible impact on: billing for patients during a global period (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, Sections 30.6.8.E and 30.6.9.2.A.); documentation requirements (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, Sections 30.6.8.C and 30.6.9.1.D.); modifiers associated with hospital inpatient or observation care claims (Medicare Claims Processing Manual, IOM 100–04, Chapter 12, Section 30.6.9.1.F); and any other issues not otherwise discussed in this proposed rule that may need to be addressed through additional guidance.

f. Prolonged Services for Hospital Inpatient or Observation Care

As part of its E/M revisions, the CPT Editorial Panel made several changes to prolonged codes that previously could be billed with inpatient or observation codes. In February 2021, the CPT Editorial Panel deleted Prolonged Service with Direct Patient Contact (Except with Office or Other Outpatient Services), including CPT code 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour; List separately in addition to code for inpatient or observation Evaluation and Management service*) and CPT code 99357 (*each additional 30 minutes*), effective January 1, 2023. Prior CPT Codebook instructions indicated that CPT codes 99356 and 99357 could be applied to hospital inpatient or observation care (CPT codes 99218 through 99236). (Refer, for example, to instructions on pages 41–42 of the 2022 CPT Codebook.)

To replace deleted CPT codes 99356 and 99357, the CPT Editorial Panel created CPT code 993X0 (*Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time.) (List separately in addition to the code of the inpatient and*

observation Evaluation and Management services). Additional guidance from the 2023 CPT Codebook states, ''Code 993X0 is used to report prolonged total time (that is, combined time with and without direct patient contact) provided by the physician or other qualified health care professional on the date of an inpatient service (that is, 99223, 99233, 99236, 99255, 99306, 99310). Prolonged total time is time that is 15 minutes beyond the time required to report the highest-level primary service.'' (2023 CPT Codebook citation forthcoming.)

We do not propose to adopt CPT code 993X0, as we believe that the billing instructions for CPT code 993X0 will lead to administrative complexity, potentially duplicative payments, and limit our ability to determine how much time was spent with the patient using claims data; these reasons are discussed in further detail below. We are instead proposing to create a single G-code that describes a prolonged service, and that applies to CPT codes 99223, 99233, and 99236. This G-code would be GXXX1:

- *GXXX1 Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report GXXX1 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0, 99415, 99416). (Do not report GXXX1 for any time unit less than 15 minutes).*

We are proposing that the GXXX1 prolonged code can only be applied to the highest-level hospital inpatient or observation care visit codes (CPT codes 99223, 99233, and 99236), and can only be used when selecting the E/M visit level based on time. In other words, we propose that a prolonged code would only be applied once the greatest amount of time for initial, subsequent, or same-day discharge visits has been exceeded. We note that this proposed policy mirrors the policy the CPT Editorial Panel will apply to CPT code 993X0 (although we are not proposing to use CPT code 993X0).

We are proposing to use GXXX1 instead of CPT code 993X0 because we disagree with the CPT instructions regarding the point in time at which the prolonged code should apply. According to the 2023 CPT Codebook, CPT code 993X0, which represents a 15-minute interval, would apply to: CPT code 99223 when a practitioner reaches 90 minutes; CPT code 99233 when 65 minutes is reached; and CPT code 99236 when 100 minutes is reached. Each of these times represent only 15 minutes more than the codes' descriptor times. We disagree with this instruction, and we believe that a prolonged code is only applicable after both the total time described in the base E/M code descriptor is complete and the full 15-minutes described by the prolonged code are complete as well. We do not believe that the CPT instructions for CPT code 993X0 align with our payment policy.

Additionally, we note that CPT code 99236, per the RUC-recommended times, includes not only 85 minutes of intraservice time (performed on the date of encounter) but an additional 12 minutes of post-service time. The RUC based this recommendation on a survey timeframe which was within 3 days of the date of encounter. We are concerned that the CPT instructions for CPT code 993X0, as it applies to CPT code 99236, would result in duplicative payment, since the 12-minute post-service time was factored into the proposed valuation of CPT code 99236. It would be inappropriate to pay for a prolonged code based on post-service time that is already accounted for in the base code. We believe that the instruction for when to apply CPT code 993X0 to base code CPT code 99236 does not accurately account for this post-service time.

We propose that the prolonged service period described by GXXX1 can begin 15 minutes after the total times (as established in the Physician Time File) for CPT codes 99223, 99233, and 99236 have been met. Additionally, we propose that the proposed GXXX1 prolonged code would be for a 15-minute increment, and the entire 15-minute increment must be completed in order to bill GXXX1. Note that for administrative simplicity, we propose to round the time when the prolonged service period begins to the nearest 5 minutes. For the times below, CPT code 99223, which has a RUC-proposed total time of 74 minutes, would be treated as though it has 75 total minutes. CPT code 99233, which has a RUC-proposed total time of 52 minutes, would be treated as though it has 50 total minutes; and CPT code 99236, which has a RUC-proposed total time of 97 minutes will be treated as though it has 95 total minutes. The rounding here is solely for the purpose of calculating a proposed prolonged period, and would not affect the total times for these CPT codes in the Time File.

Thus, a practitioner could bill GXXX1 for base code CPT code 99223 when 105 minutes is reached for an initial visit on the date of encounter. For the purposes of applying the proposed prolonged code, the CPT code 99223 total time is rounded to 75 minutes on the date of encounter. The prolonged service period would begin at 90 minutes, 15 minutes beyond 75 minutes. A practitioner would bill GXXX1 once the 15-minute increment for GXXX1 is completed, at minute 105.

A practitioner could bill GXXX1 for the base code CPT code 99233 when 80 minutes is reached for a subsequent visit on the date of encounter. For the purposes of applying the prolonged code, the CPT code 99233 total time is rounded to 50 minutes on the date of encounter. The prolonged service period would begin at 65 minutes, 15 minutes beyond 50 minutes. A practitioner would bill GXXX1 once the 15-mimute increment for GXXX1 is completed, at minute 80.

A practitioner could bill GXXX1 for base code CPT code 99236 at 125 minutes for same-day discharge. For the purposes of applying the prolonged code, the CPT code 99236 total time is rounded to 95 minutes completed within 3 calendar days of the encounter. The prolonged service period would begin at 110 minutes, 15 minutes beyond 95 minutes. A practitioner could bill GXXX1 once the 15-minute increment for GXXX1 is completed, at minute 125.

Refer to summary Table 18 in the section ''Prolonged Services Valuation'' (section II.F.11.e. of this proposed rule) for a chart showing the proposed billing timeframe for GXXX1.

We are also proposing that the proposed GXXX1 would apply to both face-to-face and non-face-to-face time spent on the patient's care within the survey timeframe. For CPT codes 99223 and 99233, this would be time spent on the date of encounter. For CPT code 99236, this would be time spent within 3 calendar days of the encounter. Because we are proposing that prolonged services without direct patient contact would be reportable under GXXX1, we are also proposing that CPT codes 99358 (*Prolonged evaluation and management services before and/or after direct patient care, first hour*) and 99359 (*each additional 30 minutes*) cannot be billed for base codes CPT codes 99221 through 99223 and 99231 through 99236. Direct patient care, as currently described by CPT codes 99358 and 99359, will be reportable under GXXX1. Allowing both GXXX1 and CPT codes 99358 and 99359 would cause confusion and invite

duplicative billing for prolonged direct patient care. This is consistent with our final policy for O/O E/M visits, which requires the use of prolonged code G2212 (*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact*) for prolonged O/O E/M services. We continue to be concerned about program integrity, duplicative payments for time counted in both E/M base codes and prolonged E/M services codes, the administrative complexity of having multiple prolonged service codes, and our ability to tell how much time was spent with the patient using claims data (see our previous discussion of these issues in our CY 2020 PFS final rule at 84 FR 62849 through 62850). If we proposed to adopt the CPT codes for prolonged inpatient and observation E/M visits, we would not be able to identify the time spent with patients in the claims data alone, because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors.

g. Valuation of Hospital Inpatient or Observation Care Services

The revised hospital inpatient or observation care codes (CPT codes 99221 through 99223 and 99231 through 99236) were surveyed for the October 2021 RUC meeting. The survey times captured the total time on the date of encounter by calendar date. In October 2021, the RUC referred these services to be resurveyed because the survey did not include a request for distinct time before and after floor/unit time, and therefore could not be compared to previous RUC surveys of these services. The RUC reviewed the resurveyed inpatient and observation services for the January 2022 RUC meeting.

We propose to accept the RUC recommendations for work RVUs and times for CPT codes 99221 (work RVU 1.63, intraservice time 40 minutes, total time 40 minutes); 99222 (work RVU 2.60, intraservice time 55 minutes, total time 55 minutes); 99223 (work RVU of 3.50, intraservice time 74 minutes, total time 74 minutes); 99231 (work RVU 1.00, intraservice time 25 minutes, total time 25 minutes), 99232 (work RVU 1.59, intraservice time 36 minutes, total time 36 minutes); 99233 (work RVU 2.40, intraservice time 52 minutes, total time 52 minutes); 99234 (work RVU 2.00, intraservice time 45 minutes, total time 50 minutes); 99235 (work RVU 3.24, intraservice time 68 minutes, total time 76 minutes); and 99236 (work RVU 4.30, intraservice time 85 minutes, total time 97 minutes).

There are no PE inputs for these codes.

4. Hospital or Observation Discharge Day Management (CPT Codes 99217, 99238 and 99239)

a. Coding Changes to Hospital Inpatient or Observation Discharge Day Management Services

Effective January 1, 2023, the CPT Editorial Panel deleted the observation discharge code, CPT code 99217 (*Observation care discharge day management*) and revised the two hospital discharge day management codes, CPT codes 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less*) and CPT code 99239 (*more than 30 minutes*) so that CPT codes 99238 and 99239 may be billable for discharge of hospital inpatient or observation patients.

We propose to adopt the revised CPT codes 99238 and 99239. We also propose to retain our current hospital inpatient policy outlined in the Medicare Claims Processing Manual, Chapter 12, 30.6.9.2.A and 30.6.9.2.E, and expand it to include observation care. Specifically, we are proposing that CPT codes 99238 and 99239 are to be billed by the practitioner who is personally responsible for discharge service (or, in the case of the death of the patient, the physician who personally performs the death pronouncement); services furnished by other practitioners, including: instructions to the patient, communication with the family/caregiver, and coordination of post discharge services would be reported as subsequent hospital inpatient or observation care with CPT codes 99231, 99232, and 99233. (Refer to the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, Manual, IOM 100–04, Chapter 12, 30.6.9.2.A and 30.6.9.2.E.) This policy aligns with instructions in the 2023 CPT Codebook (citation forthcoming).

We propose to retain our related policy that the same physician may not bill a hospital discharge CPT code 99238 or 99239 on the same day as a subsequent visit CPT codes 99231 through 99233. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.9.2.C.)

b. Prolonged Services and Hospital Inpatient or Observation Discharge Day Management

As we discussed in section II.F.3. of this proposed rule, as part of its E/M revisions, effective January 1, 2023, the CPT Editorial Panel deleted CPT code 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour*) and CPT code *99357* (*each additional 30 minutes*) and replaced them with CPT code 993X0 (*Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time*). CPT codes 99356 and 99357 were not previously billable with discharge day management CPT codes 99238 or 99239. (Refer to, for example, instructions on pages 41–42 of the 2022 CPT Codebook.) Additionally, according to 2023 CPT Codebook instructions, the CPT code 993X0 is not billable with CPT codes 99238 and 99239. (2023 CPT Codebook citation forthcoming.)

We propose that a practitioner would not be able to bill prolonged services for hospital discharge (CPT code 99238 or 99239). This means that CPT codes 993X0, 99358 (*Prolonged evaluation and management services before and/or after direct patient care, first hour*) and 99359 (*each additional 30 minutes*), and the proposed GXXX1 code (discussed in section II.F.3. of this proposed rule) would not be payable where the discharge day management code is CPT codes 99238 or 99239. We believe the code descriptors for CPT codes 99238 and 99239 do not allow for additional payment of prolonged services. The descriptor for CPT code 99238 provides for hospital discharge day management, ''30 minutes or less.'' If a practitioner spends more than 30 minutes on a hospital discharge service for a patient, the practitioner would be able to bill CPT code 99239, which is defined in the code descriptor as ''30 minutes or more.'' Thus, a prolonged code (including CPT codes 993X0, 99358, 99359, and our proposed GXXX1) would not be appropriate for CPT code 99238, because CPT code 99239 accounts for services that exceed 30 minutes.

The descriptor for CPT code 99239 states that the code is for ''30 minutes or more'' of hospital discharge day management services. When the RUC surveyed this code, the surveyed timeframe was within 3 calendar days of the encounter. In other words, the

descriptor time is 30 minutes or more, completed within 3 calendar days of the encounter. Neither the descriptor nor the CPT billing instructions provide an upper limit on how many minutes can be reported within the 3-day timeframe for CPT code 99239. All face-to-face and non-face-to-face activities performed by the practitioner during the date of encounter and within 3 calendar days from the date of encounter may be counted toward CPT code 99239, as applicable. Prolonged codes CPT codes 993X0, 99358, 99359 and our proposed GXXX1 code are intended to pay for time not included in the base E/M codes during the surveyed timeframe; as it appears that CPT code 99239 already includes all services furnished during the surveyed timeframe, we do not believe it is appropriate to allow any prolonged codes to be billed with CPT code 99239 as a base code.

c. Valuation of Hospital Inpatient or Observation Discharge Day Management

The revised discharge day management codes (CPT codes 99238 through 99239) were surveyed for the January 2022 RUC meeting. We propose to accept the RUC recommendations for CPT codes 99238 (work RVU 1.50, intraservice time 28 minutes, total time 38 minutes); and 99239 (work RVU 2.15, intraservice time 45 minutes, 64 minutes total time).

We are proposing the RUC-recommended direct PE inputs for CPT codes 99238 and 99239 without refinement.

5. Emergency Department Visits (CPT Codes 99281–99285)

a. Coding

We have revalued the ED visit codes under the PFS four times: in 1997, 2007, 2020, and most recently in 2021 as part of the update for O/O E/M visits. In the past, consistent with AMA RUC recommendations, we revalued these services such that the values of levels 1 through 3 of the ED visits were equal to levels 1 through 3 new patient O/O E/M visits, and the levels 4 and 5 ED visits were valued higher than the levels 4 and 5 new patient O/O E/M visits to reflect higher typical intensity. In addition, in the CY 2018 PFS final rule (82 FR 53018), we finalized a proposal to nominate all five ED visit codes as potentially misvalued, based on information suggesting that the work RVUs for ED visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, some impacted parties expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished. Accordingly, the RUC resurveyed and reviewed these five codes for the April 2018 RUC meeting, and provided a recommendation to CMS for consideration in CY 2020 rulemaking. In the CY 2020 PFS final rule (84 FR 62796), we finalized the RUC-recommended increases to the work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285. The RUC did not recommend, and we did not finalize, any change in direct PE inputs for the codes in this family. We note that the RUC submitted these recommended values to CMS prior to the submission of the RUC-recommended revaluation of the O/O E/M visit code family.

In response to our finalizing of the RUC-recommended values for the ED visits, and to our comment solicitation in the CY 2020 PFS proposed rule regarding whether we should revalue certain services commensurate with increases to the O/O E/M visits (84 FR 62859 through 62860), a commenter submitted a public comment stating that relativity between the ED visits and O/O E/M visits should be maintained, and submitted a specific recommendation for CPT codes 99283–99285 that was higher than the RUC-recommended values. The commenter stated we should preserve the relationship between the ED and O/O E/M visit code sets that was established in prior years and that they believe would have likely been maintained had the O/O E/M visits been reviewed prior to the ED visits. In order to avoid the rank order anomaly whereby an ED visit would be valued lower than the analogous O/O E/M visit, we proposed and eventually finalized the values recommended by this commenter in the CY 2021 PFS final rule (85 FR 84562). This final policy increased the work RVU from 1.42 to 1.60 for CPT code 99283, from 2.60 to 2.74 for CPT code 99284, and from 3.80 to 4.00 for CPT code 99285.

Following the implementation of the revisions to the O/O E/M visits for the CPT 2021 code set, the CPT/RUC Workgroup on E/M standardized the rest of the E/M sections in the CPT code set. In February 2021, the CPT Editorial Panel revised the five ED visit codes to align with the principles included in the E/M office visit services by documenting and selecting level of service based on medical decision making, effective January 1, 2023. The descriptor for CPT code 99281 was revised such that the code may not require the presence of a physician or other qualified health care professional. The CPT Editorial Panel also revised the MDM level in the descriptor for CPT code 99282 from ''low'' to ''straightforward'' complexity, and from ''moderate'' to ''low'' complexity for CPT code 99283. These five codes were resurveyed and reviewed at the April 2021 RUC meeting with recommendations submitted to CMS for the CY 2023 PFS rulemaking cycle.

b. Sites of Service and Multiple Same-Day E/M Visits for Emergency Department Patients

As we discussed in the previous section (Hospital Inpatient or Observation Care (CPT codes 99218–99236)) the CPT Editorial Panel has revised CPT codes 99221 through 99223 to include both inpatient hospital and observation care services. (Note our proposal in that section regarding billing policy for transitions between ED and hospital inpatient or observation care.) We also propose to modify our policy regarding when to bill ED codes CPT codes or hospital inpatient care (CPT codes 99221 through 99223), as further described in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.11.E., to clarify that these policies apply to observation care billed under CPT codes 99221 through 99223 as well. We are proposing that if a physician advises their own patient to go to an ED of a hospital for inpatient care or observation and the physician subsequently is asked by the ED physician to come to the hospital to evaluate the patient and to advise the ED physician as to whether the patient should be admitted to the hospital, placed in observation status, or sent home, the physicians should bill as follows:

- If the patient is admitted to the hospital or placed in observation status by the patient's personal physician, then the patient's personal physician should bill only the appropriate level of the initial hospital inpatient or observation care (CPT codes 99221–99223), because all E/M services provided by that physician in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed on the same date as the admission. The ED physician who saw the patient in the ED should bill the appropriate level of the ED codes.
- If the ED physician, based on the advice of the patient's personal physician who came to the ED to see the patient, sends the patient home, then the ED physician shall bill the

appropriate level of ED service. The patient's personal physician shall also bill the level of ED code that describes the service they provided in the ED. If the patient's personal physician does not come to the hospital to see the patient, but only advises the ED physician by telephone, then the patient's personal physician may not bill the ED codes.

Similarly, we propose that if the ED physician requests that another physician evaluate a given patient, the other physician should bill an ED visit code. We are also proposing that if the patient is admitted by the second physician performing the evaluation, that physician shall bill an initial hospital inpatient or observation care code (CPT codes 99221 through 99223, as appropriate), and not an ED visit code. This policy appears in the Medicare Claims Processing Manual, (Pub. 100–04) Chapter 12, 30.6.11.F., and we are clarifying that this policy applies to both hospital inpatient and observation care billed under CPT codes 99221 through 99223.

Finally, we note that the 2023 CPT Codebook provides instructions that critical care and ED services may be billed on the same day under certain circumstances. We refer readers to the CY 2022 PFS final rule (86 FR 65163), where we finalized our policy that critical care and ED visits may be billed on the same day if performed by the same physician, or by physicians in the same group and specialty if there is documentation that the E/M service was provided prior to the critical care service at a time when the patient did not require critical care, that the service is medically necessary, and that the service is separate and distinct, with no duplicative elements from the critical care service provided later in the day, and that practitioners may bill for both services. Practitioners must use modifier –25 on the claim when reporting these critical care services. This policy is also in the Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.12.6.

Refer to the next section, ''Nursing Facility Services'' for discussion of policies regarding patients seen in the ED and the nursing facility on the same day.

c. Valuation

We are proposing the RUC-recommended work RVU for four of the five codes in the ED Visits family. We are proposing a work RVU of 0.25 for CPT code 99281 (*Emergency department visit for the evaluation and management of a patient, that may not require the presence of a physician or other qualified health care professional*), a work RVU of 0.93 for CPT code 99282 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*), a work RVU of 1.60 for CPT code 99283 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), and a work RVU of 4.00 for CPT code 99285 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making*).

We disagree with the RUC-recommended work RVU of 2.60 for CPT code 99284 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*) and we are proposing to maintain the current work RVU of 2.74. The survey conducted for CPT code 99284 maintained unchanged a work time of 40 minutes, and the level of medical decision making in the code's descriptor also remains unchanged at ''moderate'' complexity. Therefore, we continue to believe that the levels 4 and 5 ED visits are more accurately valued higher than the levels 4 and 5 new patient O/O E/M visits to reflect their higher typical intensity. This has been the historic relationship between these codes, and we previously finalized a proposal in the CY 2021 PFS final rule, increasing the work RVU from 2.60 to 2.74 for CPT code 99284. Given that there has been no change in the surveyed work time or level of MDM for this service, we continue to believe that the work RVU of 2.74 that we finalized in the CY 2021 rule cycle remains the most accurate valuation for CPT code 99284 (85 FR 84562).

The RUC did not recommend and we are not proposing any direct PE inputs for these five ED visit codes.

d. Prolonged Services

We are proposing that the prolonged services described by HCPCS codes GXXX1–GXXX3 would not be reportable in conjunction with ED visit codes, because the ED visit codes are not reported based on the amount of time spent with the patient. This proposal is reflected in summary Table 18 in section II.F.11.e. of this proposed rule.

6. Nursing Facility Visits (CPT Codes 99304–99318)

a. Coding Overview

The codes in the Nursing Facility (NF) services family are used to report E/M services primarily to patients in nursing facilities and skilled nursing facilities. Following the implementation of the revisions to the O/O E/M visits (CPT codes 99201 through 99215) for the CPT 2021 code set, the CPT/RUC Workgroup on E/M met to standardize the rest of the E/M sections in the CPT code set. We have received valuation recommendations from the AMA RUC for the Nursing Facility Visit codes (CPT codes 99304 through 99318) following completion of its survey and revaluation process for these codes. In April 2021, the RUC provided us the results of its review, and recommendations for work RVUs, practice expense inputs, and physician time (number of minutes) for the revised Nursing Facility Visits E/M code set. Therefore, we are proposing changes in coding and values for the revised Nursing Facility Visits E/M code set. This code set is effective beginning in CY 2023, and the proposed values, if finalized, would go into effect with those codes as of January 1, 2023. In February 2021, the CPT Editorial Panel deleted CPT code 99318, the annual nursing facility assessment code and revised the remaining nursing facility code to better align with the principles included in the E/M office visit services by documenting and selecting level of service based on total time or MDM. The remaining codes, initial and subsequent daily visits and nursing facility discharge day management codes were revised. Similar to what was done for the office visit codes, for CY 2023, we are proposing when total time on the date of encounter is used to select the appropriate level of a nursing facility visit service code, both the face-to-face and non-face-to-face time personally spent by the physician (or other qualified health care professional that is reporting the office visit) assessing and managing the patient are summed to select the appropriate code to bill. Additionally, the codes have new descriptor times, assigned for when time is used to select visit level. (We note that we are not adopting the CPT Codebook instructions regarding the application of prolonged codes to CPT codes 99306 and 99310; see additional discussion under the subsection ''Prolonged Codes for NF Care'' in this section.) Initial nursing facility care (CPT codes 99304 through 99306) may be used once per admission, per practitioner, regardless of the length of

stay in the SNF/NF. (2023 CPT Codebook citation forthcoming.)

These nursing facility visits are noted by the RUC to be typically performed in the skilled nursing facility which requires a higher level of care than the nursing facility. The survey time captured includes pre-service time 1 day before the date of encounter, intra-service time is all the time on the date of encounter, and post-service time is 3 days after the date of encounter. The RUC's recommendations for this code family are consistent with the 25th percentile of the survey results and is based on a comparison of the survey codes with the selected the O/O CPT codes as a crosswalk to the key reference services.

While we have thoroughly reviewed the times and descriptors for all the codes in this family, and we are proposing to accept the RUC recommendations as explained below, we would like to note our concerns regarding instances of inconsistencies and errors where the time described in certain CPT code descriptors does not correctly relate to the time that would be used to select visit level for the Nursing Facility visit, for example CPT code 99306 and 99310 have the same times noted in the descriptors where one is an initial visit and one is a subsequent visit. In general, the specialty societies and the RUC have advocated for increasing the work RVUs for the Nursing Facility visits, as compared to their previous values, regardless of some of the survey times, on the basis that values for these Nursing Facility visit codes should be valued the same as the values for the comparable O/O E/M visits. We considered the survey results, especially reductions in pre, intra, and post service time and note that the comparison to O/O E/M visits is not accurate. These code families are incomparable for a few reasons, including, but not limited to: (1) the two families have a different number/stratification of levels for the visits, thus a one-to-one crosswalk is not possible; (2) times in the code descriptors detailing the typical time spent at the patient's bedside or hospital unit vary significantly; and (3) the patient populations differ substantially when considering typical patients who require nursing facility services versus those in the general beneficiary community. Additional reasons are laid out in our overview section above. We do not believe that a comparison of these two code families can technically be made on a code-by-code basis. However, given the recent changes to the O/O E/M visit values that we finalized in the CY 2020 PFS final rule (84 FR 62846), and our interest in maintaining continuity in the overall code set, we are proposing to accept the RUC recommendations for the work time values and work RVUs for these Nursing Facility visit codes and are seeking public comment on our concerns for some of the codes as noted below in this section.

We are proposing to adopt a number of billing policies reflected in our current Medicare Claims Processing Manual, Chapter 12, section 30.6.13:

- We are proposing that the initial comprehensive assessment required under 42 CFR 483.30(c)(4) shall be billed as an initial NF care visit (CPT code 99304 through 99306). We propose that a practitioner may bill the most appropriate initial nursing facility care code (CPT codes 99304 through 99306) or subsequent nursing facility care code (CPT codes 99307 through 99310), if the practitioner furnishes services that meet the code descriptor requirements, even if the service is furnished prior to the initial comprehensive assessment required under § 483.30.

A practitioner who bills an initial NF visit (CPT codes 99304 through 99306) for the initial comprehensive assessment required under § 483.30(c)(4) may bill subsequent NF visits (CPT codes 99307 through 99310), if the practitioner furnishes medically necessary face-to-face and non-face-to-face care that meets the requirements in the NF services code descriptors (CPT codes 99307 through 99310) to the beneficiary prior to the completion of the initial comprehensive assessment required under § 483.30. We are proposing to allow for an initial or subsequent NF visit to be furnished and billed by the appropriate practitioner (physician, physician assistant, nurse practitioner, or clinical nurse specialist as specified in § 483.30 for the type of visit furnished) regardless of whether the initial comprehensive assessment was performed.

- We propose to retain our policy to not pay a physician for an ED visit or an office visit and a comprehensive nursing facility assessment on the same calendar day, because it would be duplicative care. If the practitioner saw the patient in the nursing facility once on a given date, they have performed a lot of the work that is included in the other visit E/M visits, for example an ED visit. The services furnished on the same date and provided in sites other than the nursing facility are already bundled into the initial nursing facility care code when performed on the same date as the nursing facility admission by the same physician.

We note that the Medicare Claims Processing Manual also states that ED visits provided on the same day as a comprehensive nursing facility assessment are not paid, regardless of whether the ED and nursing facility visits are by the same or different practitioners. We are proposing to retain this policy as well. We note that the 2023 CPT Codebook does not limit the number of visits that can be billed (citation forthcoming.) We are proposing that more than one ED and nursing facility visit could not be billed if both visits are furnished by the same practitioner on the same date of service.

- We propose to adopt the 2023 CPT Codebook guidance that, for reporting initial nursing facility care, transitions between skilled nursing facility level of care and nursing facility level of care do not constitute a new stay. (2023 CPT Codebook citation forthcoming.)
- We propose that an initial service is one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay. We propose that a subsequent service is one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty who belongs to the same group during the stay. This is the same definition that we propose for ''initial'' and ''subsequent'' in the context of inpatient and observation services above. According to CPT instructions, an ''initial'' service may be reported when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay. As we do not recognize subspecialties, we propose to apply these slightly amended definitions of ''initial'' and ''subsequent'' service.

b. Valuation

For CPT codes 99304 through 99310, we are proposing to adopt the RUC-recommended work RVUs for all of the nursing facility codes given the new times surveyed by the RUC and specialty societies. Specifically, we are proposing a work RVU of 1.50 for CPT code 99304 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which*

requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.), a work RVU of 2.50 for CPT code 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), a work RVU of 3.50 for CPT code 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*), a work RVU of 0.70 for CPT code 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*), a work RVU of 1.30 for CPT code 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*), a work RVU of 1.92 for CPT code 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*), and a work RVU of 2.80 for CPT code 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*). We are proposing the RUC-recommended direct PE inputs for all the codes in the family, CPT codes 99305 through 99310.

While we are proposing to accept the RUC recommendations for CPT code 99306, we considered maintaining the current work RVU of 3.06, since there was no change in the overall time. To support their recommendation, the RUC cited the survey key reference service, CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter*), which has a much higher time noted in the descriptor and does not seem to be a valid comparison or support the increase in value to the RUC survey 25th percentile. There was no change in time for this service, and the code the RUC used for comparison has a higher total time. Therefore, we request comment on the accuracy of the time noted in the descriptor for CPT code 99306. We note that it is not clear to us why CPT code 99306 would have the same descriptor time and medical decision making as CPT code 99310, which is a subsequent visit, thus appearing like they are the same service. We are seeking clarification, especially with regard to the vast similarities of these two descriptors noted for these services.

For CPT code 99308, we are proposing to accept the RUC recommendations; however, we considered maintaining the current work RVU of 1.16 given there was a decrease in the total time for the service and no change in the descriptor time. We are soliciting comment regarding the RUC recommendations that the total time be rounded down to 15 minutes instead of rounding up to twenty minutes, when using total time on the date of the encounter for code selection (minutes must be met or exceeded), and are seeking clarification on this difference. In light of the changes made to the O/O E/M visits, however, we are proposing the RUC-recommended work RVU of 1.30 for CPT code 99308, but would appreciate comments regarding rounding.

For CPT code 99309, we are proposing a work RVU of 1.92. When compared to CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*), we are acknowledging the increase in time required to bill CPT code 99309. We note that the descriptor time for CPT code 99309 went up since these codes were last revalued. We are focusing on the time in the descriptor, and if there is a change in the level of MDM. In light of recent changes made to the O/O E/M visits, however, we are proposing the RUC-recommended work RVU of 1.92 for CPT code 99309.

Although we are proposing to adopt all the RUC-recommended work RVUs and times for this code family as explained above, we are seeking comment regarding the discrepancies in times, which have implications both for valuation of individual codes (and for PFS ratesetting in general), since the intraservice times and total times are used as references for valuing many other services under the PFS. After reviewing the RUC recommendations, in conjunction with the revised code descriptors and documentation guidelines for CPT codes 99304 through 99310, we are proposing to accept the RUC-recommended work and time values for the revised nursing facility visit codes with the PE refinements noted by the RUC for CY 2023.

c. Prolonged Services

We are proposing that prolonged nursing facility services by a physician or NPP would be reportable under GXXX2, which would be used when the total time (in the time file) is exceeded by 15 or more minutes to account for the additional time spent. The long descriptor would be *GXXX2* (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report GXXX2 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report GXXX2 for any time unit less than 15 minutes)).* We propose that the practitioner would include any prolonged service time spent within the surveyed timeframe, which includes the day before the visit, the day of the visit, and up to and including 3 days after the visit (please see summary Table 18 in section II.F.11.e. of this proposed rule). We are proposing that prolonged physician or NPP NF services would be reportable when the total time (in the physician time file) is exceeded by 15 or more minutes which would be once 95 minutes are spent for initial NF visits, and once 85 minutes are spent for subsequent NF visits, and for each additional 15 minutes furnished thereafter. Consistent with CPT coding

guidance as indicated below, there would not be any frequency limitation; therefore, we are proposing that physicians and NPPs would be able to bill GXXX2 for each additional 15-minute increment of time beyond the total time for CPT codes 99306 and 99310.

Since GXXX2 includes time without direct patient contact, there would no longer be a need to use CPT codes 99358 and 99359 (prolonged E/M visit without direct patient contact) in conjunction with NF visits. Therefore, we are proposing to change the payment status for CPT codes 99358 and 99359 to ''I'' (*Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services*). This is consistent with our final policy for O/O E/M visits, where prolonged time can no longer be reported using CPT codes 99358 and 99359. We continue to be concerned about program integrity, counting time that was not included in the surveyed timeframe, and the administrative complexity of having multiple prolonged service codes associated with a given primary service (see our previous discussion of these issues in our CY 2020 PFS final rule at 84 FR 62849 through 62850). As we stated in that rule, many other codes are available to report prolonged E/M work associated with an E/M visits that occurs outside of the timeframe included in the visit, such as CCM, TCM, PCM, behavioral health integration (BHI), and other care management service codes. We designed these codes to be used to report time spent outside the direct patient contact (but still in management/consideration of that given patient's case) on dates other than the E/M visit. While these care management codes are not identical to the prolonged visit codes, they can be used to report a number of similar activities. Additional information about those codes can be found on our PFS Care Management website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.* We also direct the reader to section II.E of this proposed rule, where we propose additional care management service codes for pain management and BHI.

When prolonged nursing facility services are furnished by a physician or NPP, they would be reportable under GXXX2. We believe that allowing practitioners to report CPT code 993X0 after the minimum time requirement for the highest level subsequent visit is met and then exceeded by at least 15 minutes would result in double counting time. As a specific example, CPT code 99310 requires that 45 minutes must be met or exceeded up to 60 minutes. If the reporting practitioner spent 55 minutes of time, those 55 minutes would be billed and are included in the services described by CPT code 99310. After 60 minutes has been met, any additional time should be counted toward the 15 minutes required to report the add on CPT code for the prolonged service. Similar to the policy we finalized in the CY 2020 PFS final rule for the O/O E/M visits (84 FR 62849), which states that when the time of the reporting physician or NPP is used to select O/O E/M visit level, HCPCS code G2212 could be reported when the maximum time for the level 5 O/O E/M visit is exceeded by at least 15 minutes on the date of service.

In addition, we note that the CPT code descriptor for CPT code 993X0 does not include nursing facility. Further, the timeframes do not align for CPT codes 993X0, 99358, and 99359. The survey time for CPT code 993X0 is for time on the date of service, and when the nursing facility visit codes were resurveyed by the RUC, the survey time included the day before, the day of, and up to and including 3 days post the date of service. We are proposing Medicare-specific coding in order to avoid duplicative counting of time, administratively simplify prolonged service coding, and better enable us to determine how much total time was spent with the patient. If we proposed to merely accept the CPT prolonged service coding changes, we would not be able to identify the time spent with patients in the claims data alone. This is because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. Consistent with CPT's approach, we are proposing that practitioners and NPPs would only be able to report the prolonged services code for NF (GXXX2) in conjunction with the highest level codes in the family (CPT code 99306 and 99310). This would also be consistent with our policy for O/O E/M visits (see (84 FR 62849).

7. Nursing Facility Discharge Management (CPT Codes 99315–99316)

a. Coding

CPT codes 99315 (*Nursing facility discharge day management; 30 minutes or less*) and 99316 (*Nursing facility discharge day management; more than 30 minutes*) were identified for RUC review in October 2021 and were then postponed so that they could be reviewed at the same time as the inpatient hospital and observation care codes, in January 2022. Due to changes in physician work, changes in technology, patient population, and length of stay, the RUC determined that the nursing facility discharge services could be reviewed separately from the inpatient hospital discharge day services.

The nursing facility discharge day management codes are used to report the total duration of time spent by a physician or other qualified health care professional for the final nursing facility discharge of a patient. The codes include, as appropriate, final examination of the patient and discussion of the NF stay, even if the time spent on that date is not continuous. Instructions are given for continuing care to all relevant caregivers, as well as for preparation of discharge records, prescriptions, and referral forms. These services require a face-to-face encounter, which may be performed on a calendar date prior to the actual discharge date. The time of the face-to-face encounter performed on a date prior to the discharge date is counted toward CPT code 99315 and CPT code 99316 and not reported separately.

We propose to retain our policy that CPT codes 99315 and 99316 (as appropriate) shall be reported for a face-to-face visit with the patient provided by the physician or the qualified NPP, which is required in order to report the SNF/NF discharge day management service. The NF discharge day management visit shall be reported for the date of the actual visit by the physician or qualified NPP, even if the patient is discharged from the facility on a different calendar date. (Refer to Medicare Claims Processing Manual, IOM 100–04, Chapter 12, 30.6.13.I.) Additionally, we are proposing that a physician or qualified NPP may report CPT codes 99315 or 99316 for a patient who has expired only if the physician or qualified NPP personally performed the death pronouncement.

b. Valuation

We are proposing the RUC-recommended work RVU of 1.50 for CPT code 99315. We considered maintaining the current work RVU of 1.28 for CPT code 99315, based on the total time ratio between the current time of 40 minutes and the recommended time established by the survey of 40 minutes. Utilizing our total time ratio methodology this ratio equals 100 percent, and 100 percent of the current

work RVU of 1.28, which indicates there is no change to the physician service and no change in the physician total time. We believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In this case, there was no change in total time. However, maintaining CPT code 99315 at the current value of a work RVU of 1.28 would cause a rank order anomaly with CPT code 99308. Also, given the remaining NF codes were revised to align with the principles included in the O/O E/M visit services by documenting and selecting level of service based on total time or MDM, we concluded that the increase of the work RVU to 1.50 for CPT code 99315 would be appropriate.

We are proposing the RUC-recommended work RVU of 2.50 for CPT code 99316. We considered proposing a work RVU of 2.22 based on the total time ratio between the current time of 54 minutes and the recommended time established by the survey of 63 minutes. When we reviewed CPT code 99316, we found that the recommended work RVU was higher than nearly all of the other global XXX codes with similar time values, and we do not believe that this code would have an anomalously high intensity. As we stated earlier, in light of changes made to the O/O E/M visits and the changes to include documenting and selecting level of service based on total time or MDM, we are proposing the RUC-recommended work RVU of 2.50 for CPT code 99316. We are proposing the RUC-recommended direct PE inputs for CPT code 99315 and the RUC-recommended direct PE inputs for CPT code 99316.

c. Prolonged Services

CPT code 99315 and CPT code 99316, the two codes for nursing facility discharge management, are set up as a base code with an add-on code with no ceiling of time. Since time on any day can be included when billing CPT code 99315 or 99316, there is no need for a prolonged service code for either of these two codes. Allowing for a prolonged service code for either of these two codes could result in double counting a physician or NPP's time spent during a nursing facility discharge, which would not be appropriate. Additionally, CPT code 993X0 does not include Nursing Facility in the descriptor. Therefore, we are proposing that prolonged services would not be reportable in conjunction with CPT codes 99315 and 99316 (NF discharge day management).

8. Annual Nursing Facility Assessment (CPT Code 99318)

a. Coding

CPT code 99318 (*Evaluation and management of a patient involving an annual nursing facility assessment, which requires these 3 key components: A detailed interval history; A comprehensive examination; and Medical decision making that is of low to moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 30 minutes are spent at the bedside and on the patient's facility floor or unit*) was recommended for deletion by CPT for 2023. In February 2021, the CPT Editorial Panel deleted CPT code 99318 and revised seven nursing facility codes to align with the principles included in the O/O E/M visits by documenting and selecting level of service based on total time or MDM.

We are proposing to accept CPT's deletion of CPT code 99318. Our longstanding manual guidance states that an annual nursing facility assessment visit code may substitute as meeting one of the required physician visits, as specified in 42 CFR 483.30 (c)(1), if the code requirements for CPT code 99318 are fully met (Medicare Claims Processing Manual (Pub. 100–04) chapter 12, section 30.6.13 (B)). Due to the longstanding nature of the manual section, we believe some provisions may be outdated, and it is possible to satisfy this requirement through other codes. We are seeking comment on whether there is a need to keep this code for Medicare purposes. As we consider accepting the CPT's deletion of CPT code 99318, we are concerned that the absence of a similar code could cause an unwarranted increase in valuation of other services under the PFS, and CMS would not have a means of tracking how often these visits are occurring. While CPT code 99308, CPT code 99309, and CPT code 99310 could be used to report the required annual visit, if we were to accept deletion of CPT code 99318, we believe most of the utilization for that former code would instead be reported under CPT code 99309, with a RUC-recommended work RVU of 1.92 which is described in the valuation section below.

b. Valuation

After considering the utilization and the need for the service described by CPT code 99318, we are proposing to accept the CPT's deletion of CPT code 99318. Given the proposed deletion for CPT code 99318, the RUC recommends that 10 percent of the CPT code 99318 utilization would go to CPT code 99308, with a work RVU of 1.16; 85 percent of the utilization would go to CPT code 99309, with a work RVU of 1.55; and 5 percent of the utilization would go to CPT code 99310, with a work RVU of 2.35.

9. Home or Residence Services (CPT Codes 99341, 99342, 99344, 99345, 99347–99350)

a. Coding

In February 2021, the CPT Editorial Panel deleted the nine CPT codes in the Domiciliary, Rest Home (for example, Boarding Home), or Custodial Care Services code family (CPT codes 99324–99328, and 99334–99337), and one CPT code in the Home Services family (CPT code 99343), to merge these services with the eight remaining home visit services. The eight remaining home services CPT codes (99341, 99342, 99344, 99345, and 99347–99350) were revised to describe Home or Residence Services to align with the principles of the O/O E/M visit codes by allowing physicians and NPPs to document and select the level of service based on total practitioner time or MDM level. For CY 2023, the home and domiciliary E/M code family will be revised by the CPT to include services provided in assisted living facilities, group homes, custodial care facilities, and residential substance abuse treatment facilities, as well as a patient's home. These changes include combining the domiciliary and rest home CPT codes with the home visit CPT codes, resulting in a single family of CPT codes that describe these types of services. In addition, CPT revised the descriptors to allow reporting that is based on time or MDM level—in alignment with the O/O E/M visit CPT codes. The RUC survey time includes pre-service time 3 days before the date of encounter, intraservice time on the date of encounter, and post-service time that includes 7 days after the date of encounter. These eight CPT codes were reviewed at the October 2021 RUC meeting with recommendations submitted to CMS for the CY 2023 rule cycle. The RUC recommended the survey 25th percentile value for all CPT codes in the Home or Residence Services code family, except for CPT code 99350, for which the RUC recommended the median value.

b. Valuation

We are proposing the RUC-recommended work RVU for all eight CPT codes in the Home or Residence Services CPT code family. We are proposing a work RVU of 1.00 for CPT code 99341 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*), a work RVU of 1.65 for CPT code 99342 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), a work RVU of 2.87 for CPT code 99344 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*), a work RVU of 3.88 for CPT code 99345 (*Home or residence visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making*), a work RVU of 0.90 for CPT code 99347 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination straightforward medical decision making*), a work RVU of 1.50 for CPT code 99348 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making*), a work RVU of 2.44 for CPT code 99349 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making*), and a work RVU of 3.60 for CPT code 99350 (*Home or residence visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making*).

We are proposing the RUC-recommended direct PE inputs for CPT codes 99345, and 99347–99350 without refinement. For CPT codes 99341 and 99342, we are refining the direct PE inputs by removing supply item SK062 (patient education booklet). For CPT code 99344, we are refining the direct PE inputs by removing supply items SK062 (patient education booklet), SJ053 (swab-pad, alcohol), and SJ061 (tongue depressor). Per the PE Summary of Recommendations provided by the RUC, CPT codes 99341, 99342, 99344, and 99347 would typically have procedures performed on the same date of service. For those CPT codes, the RUC stated that they removed supplies that would be duplicative, such as gloves, alcohol wipes, booklet, and tongue depressor. However, we found that not all of these duplicative supplies had been removed from CPT codes 99341, 99342, and 99344 by the RUC. Therefore, we are proposing to remove these duplicative supplies from CPT codes 99341, 99342, and 99344, and accept the remaining RUC-recommended direct PE inputs without refinement.

c. Prolonged Services for Home or Residence Services

We are proposing that prolonged home or residence services by a physician or NPP would be reportable under GXXX3 (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report GXXX3 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report GXXX3 for any time unit less than 15 minutes)*). Code GXXX3 would be reportable when the total time (in the time file) is exceeded by 15 or more minutes. Prolonged services (whether on the same date or another date within the surveyed timeframe) would be reportable as an add-on code to CPT codes 99345 or 99350 once the practitioner spends 15+ minutes beyond the total time finalized for the primary service (in time file). We would allow the physician or NPP to include any prolonged service time spent within the surveyed timeframe for the home or residence services code family, which includes pre-service time 3 days before the date of encounter, intraservice time on the date of encounter, and post-service time that includes 7 days after the date of encounter. This means that for CPT code 99345, assuming we finalize the RUC-recommended total time of 126 minutes, prolonged services would be reportable once 141 or more minutes are spent by a physician or NPP providing home or residence services. Likewise, for CPT code 99350, assuming we finalize the RUC-recommended total time of 97 minutes, prolonged services would be reportable once 112 or more minutes are spent by a physician or NPP providing home or residence services. See Table 18 in section II.F.11.e. of this proposed rule for a table summarizing this information.

Since we are proposing that prolonged services with or without direct patient contact would be reportable under GXXX3, we are also proposing that CPT codes 99358 (*Prolonged evaluation and management service before and/or after direct patient care; first hour*), 99359 (*Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (List separately in addition to code for prolonged service)*), and 99417 (*Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the outpatient Evaluation and Management services)*) cannot be billed for CPT codes 99345 and 99350. We are proposing to change the status indicator for CPT codes 99358 and 99359 to ''I,'' which indicates that these codes are not valid for Medicare purposes, and that Medicare uses another code for reporting of, and payment for, these services.

We continue to be concerned about program integrity, duplicative time, counting time that was not included in the surveyed timeframe, the administrative complexity of having multiple prolonged service codes, and our ability to determine how much time was spent with the patient using claims data. If we proposed to merely accept the CPT coding for prolonged home or residence E/M visits, we would not be able to identify the time spent with patients in the claims data alone. This is because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. See our previous discussion of these issues in our CY 2020 PFS final rule at 84 FR 62849 through 62850. As we stated in that rule, many other codes are available to report prolonged E/M work associated with an E/M visits that occurs outside of the timeframe included in the visit, such as CCM, TCM, PCM, behavioral health integration (BHI), and other care management service codes. We designed these codes to be used to report time spent outside the direct patient contact on dates other than the E/M visit. While

these care management codes are not identical to the prolonged visit codes, they can be used to report a number of similar activities. Additional information about those codes can be found on our PFS Care Management web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.* We also direct the reader to section II.E. of this proposed rule where we propose additional care management service codes for pain management and BHI.

10. Cognitive Assessment and Care Planning (CPT Code 99483)

a. Coding and Valuation

In February 2021, the CPT Editorial Panel revised CPT code 99483 to replace ''50 minutes'' from its descriptor with a revised time value determined by the RUC survey to align with the principles underlying the O/O E/M CPT codes. The 2023 descriptor time for CPT code 99483 will be 60 minutes typical time instead of 50 minutes typical time.

Due to the increase in the valuation for O/O E/M visits in the CY 2021 PFS final rule (85 FR 84556), we finalized a proposal to increase the value of CPT code 99483 from 3.44 to 3.80 work RVUs as a service that is analogous to the O/O E/M visits, because CPT code 99483 includes a high-level O/O E/M visit. We stated that 99483 includes an evaluation of a patient's cognitive functioning and requires collecting pertinent history and current cognitive status, all of which require MDM of moderate or high complexity. To not create a rank order anomaly with CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter*) we increased 99483 by using the ratio of the increase between the CY 2020 and CY 2021 values for 99205 to commensurate with the increase to CPT code 99205.

We are not proposing the RUC-recommended work RVU of 3.50, because we continue to believe that this service is appropriately valued more highly than the analogous O/O E/M visit code, CPT code 99205. Given what we view as the appropriate rank order among these services, we do not believe a reduction in work RVU, especially with a ten-minute increase in physician time, is warranted. In the interest of supporting access to this service, we are instead proposing a slight increase from the current 3.80 to 3.84 to account for the increase in physician time with use of a total time ratio: we divide the RUC-recommended total time of 86 by the current total time of 85 and then multiply the product by the current work RVU of 3.80 to arrive at 3.84. We are proposing the RUC-recommended PE inputs without refinement.

b. Prolonged Services

We are proposing that prolonged services would not be reportable in conjunction with CPT code 99483, because it has a typical time in its descriptor, which is not necessarily the actual time spent. Accordingly, we would not know when the prolonged services exceeded the service time.

11. Prolonged Services Valuation

a. Prolonged Services With Direct Patient Contact (CPT Codes 99354–99357)

The CPT Editorial Panel is deleting CPT codes 99354–99357 (*prolonged services with direct patient contact (except with office or other outpatient services)*). These codes are currently used to report prolonged E/M visit time involving direct patient contact, by physicians or NPPs, beyond the usual service, in settings other than O/O settings. We are proposing to accept this deletion, since this work would be reported instead under the Medicare-specific codes that we are proposing for prolonged physician/NPP time, discussed in each family's section above.

b. Prolonged Services on a Different Date Than the E/M (CPT Codes 99358–99359)

We note that the RUC resurveyed and provided recommendations to revalue these codes. However, we are proposing to assign an inactive status to these codes for purposes of PFS payment as discussed above.

c. Prolonged Services Clinical Staff Services (CPT Codes 99415 and 99416)

CPT code 99415 was created to describe the first hour of prolonged clinical staff services provided in addition to an office E/M visit, while CPT code 99416 was created to describe each additional 30 minutes beyond that first hour of prolonged clinical staff service time that was provided in addition to the O/O E/M visit. For these codes, we are proposing the RUC-recommended direct PE inputs without refinement.

d. Valuation of Prolonged Other E/M Services (HCPCS Codes GXXX1, GXXX2 and GXXX3)

As discussed above in the Overview section, we do not agree that there is inherently greater complexity of patient need or intensity of work for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) compared to the office settings. Therefore, we believe it would be more accurate to make payment based on the same time increment of physician work in these various settings. We are proposing that the three prolonged visit HCPCS G codes GXXX1–GXXX3 (discussed above under each applicable family) be valued identically across settings, based on the RUC recommended value for CPT code 99417. Therefore, we are proposing a work RVU of 0.61 for these codes with a crosswalk to CPT code 99417. We are likewise proposing direct PE inputs for these three codes that are identical to the RUC-recommended PE inputs for CPT code 99417. For the purposes of ratesetting, our utilization for these services will include the assumption that one third of the services currently reported with 99356 will be reported with each of HCPCS codes GXXX1, GXXX2, and GXXX3, and one third of the services currently reported with 99357 will be reported with each of HCPCS codes GXXX1, GXXX2, and GXXX3. We will continue to use HCPCS code G2212 previously finalized in lieu of CPT code 99417.

e. Summary of Proposed Time Thresholds To Report Other E/M Prolonged Services

Table 18 summarizes the proposed rules for reporting Other E/M prolonged services by physicians or NPPs (See each family section above for detailed proposal information).

TABLE 18: Proposed Time Thresholds to Report Other E/M Prolonged Services

Primary E/M Service	Prolonged Code*	Time Threshold to Report Prolonged	Count physician/NPP time spent within this time period (surveyed timeframe)
Initial IP/Obs. Visit (99223)	GXXX1	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	GXXX1	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	GXXX1	125 minutes	Date of visit to 3 days after
IP/Obs. Discharge Day Management (99238-9)	n/a	n/a	n/a
Emergency Department Visits	n/a	n/a	n/a
Initial NF Visit (99306)	GXXX2	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	GXXX2	85 minutes	1 day before visit + date of visit +3 days after
NF Discharge Day Management	n/a	n/a	n/a
Home/Residence Visit New Pt (99345)	GXXX3	141 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	GXXX3	112 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning	n/a	n/a	n/a
Consults	n/a	n/a	n/a

* Time must be used to select visit level. Prolonged service time could be reported when furnished on any date within the primary visit's surveyed timeframe, and would include time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we would not assign a frequency limitation.

12. Consultations (CPT Codes 99241–99255)

The RUC revised code descriptors, deleted two codes, and revalued the RVUs of the consultation codes during its October 2021 and January 2022 RUC meetings. We did not review the RUC recommendations for the eight revised consultation codes (CPT codes 99242, 99243, 99244, 99245, 99252, 99253, 99254, and 99255). We note that CMS stopped paying for the consultation codes beginning in CY 2010. We refer readers to 74 FR 61767 through 61775 where we discuss our payment policy for these services.

13. Payment for Multiple Same-Day Visits

Our manuals include many longstanding policies regarding when more than one Other E/M visit can be billed by the same practitioner for the same patient on the same date of service, particularly when a patient is being transferred among multiple care settings (see the Medicare Claims Processing Manual (Pub. 100–04), Chapter 12, which is available on our website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*). In contrast, CPT reporting instructions do not place any limitations on the number of visits that can be billed. We are proposing our longstanding manual policies for same-day visits (at Pub. 100–04, chapter 12, *et al,* per topic section), and refer the reader to the sections above regarding its application to each individual Other E/M family.

14. Split (or Shared) Services

The split (or shared) ''substantive portion'' policy for services furnished in facility settings was reflected in subregulatory guidance until it was withdrawn in May of 2021, in response to a petition under the Good Guidance regulation. In the CY 2022 PFS final rule (86 FR 65150 through 65159) we finalized a policy for E/M visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP provide the service together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. Commenters were generally supportive of our proposals with some divide with regard to our proposed definition of substantive portion. Some commenters preferred the use of MDM or one of the three key visit components as opposed to time for purposes of defining what is the substantive portion of the service.

a. Background

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. In the non-facility (for example, office) setting, the rules for ''incident to'' billing apply under this circumstance. However, ''incident to'' services are not available for services furnished in a facility setting. Longstanding CMS policy has been that, for split (or shared) visits in the facility (for example, hospital) setting, the physician can bill for the services if they perform a substantive portion of the encounter. Section 1833(a)(1)(N) of the Act specifies that payment is made for services furnished and billed by a physician at 100 percent of the PFS rate, while under section 1833(a)(1)(O)(i) of the Act, NPPs are paid for the services they furnish and bill for at a reduced PFS rate (85 percent of the PFS).

We defined substantive portion in the CY 2022 PFS final rule (86 FR 65152 through 65156) and provided for billing of split (or shared) visits in certain settings (86 FR 65156 through 65157) and for certain patient types (new and established) (86 FR 65156). After consideration of the public comments on the CY 2022 PFS proposed rule, we finalized a phased in approach to this policy (86 FR 65153). For CY 2022, we finalized the definition substantive portion as one of the following: history, or exam, or MDM, or more than half of total time. In the CY 2022 PFS final rule (86 FR 65152 and 65153), we finalized

that for CY 2023, the definition of substantive portion as being more than half of total time.

As part of our ongoing engagement with interested parties, we are hearing continued concern about the implementation of our phased in approach with regard to using only more than half of the total time to define the substantive portion of the visit, and continue to receive requests that we continue to recognize MDM as the substantive portion. Many of these concerns relate to practice patterns where the physician does not spend half or more of the time with the patient, as well as possible adjustments needed to the practice's internal processes or information systems to track visits based on time, rather than MDM. After consideration, we are proposing to delay implementation of our definition of the substantive portion as more than half of the total time until January 1, 2024. We continue to believe it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time, and propose that this policy will be effective beginning January 1, 2024. While we continue to believe that the definition of substantive portion we finalized in the CY 2022 PFS final rule is appropriate, delaying implementation of this aspect of our policy would also allow for the changes in the coding and payment policies for Other E/M visits to take effect for CY 2023, and allows for a one-year transition for providers to get accustomed to the new changes and adopt their workflow in practice. Additionally, this delay allows interested parties another opportunity to comment on this policy, and gives us time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy. To reflect the proposed delay, we are proposing to amend our regulations text at 42 CFR 415.140 to revise the definition of substantive portion, and note the current definition of substantive portion applies for visits other than critical care visits furnished in CY 2022 and CY 2023.

We are amending § 415.140 by adding to paragraph (a) ''and 2023'' after the phrase ''For visits other than critical care visits furnished in calendar year 2022''. Therefore, the proposed paragraph would specify, for visits other than critical care visits furnished in calendar year 2022 and 2023, *substantive portion* means one of the three key components (history, exam or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit.

15. Technical Correction to the Conditions for Payment: Split (or Shared) Visits

In the CY 2022 PFS final rule (86 FR 64996), we finalized our definition of split (or shared) visits as proposed, and codified it in a new section of our regulations at § 415.140. We established regulation text for this definition of split (or shared) visits. We subsequently discovered an inadvertent typographical error in the instructions we used to codify the new regulation at § 415.140. Specifically, we added the regulation text for § 415.140 under Subpart D, Physician Services in Teaching Settings, rather than Subpart C, Part B Carrier Payments for Physician Services to Beneficiaries in Providers. Because this regulation was inadvertently included with policies relating to teaching physician services, and is more appropriately placed with other policies relating to payment for physicians' services to beneficiaries in providers, we propose to revise our regulation to correct this error. As such, we propose to amend part 415 subpart D by removing the regulation at § 415.140 and relocating that section to subpart C, such that subpart D will then begin at § 415.150.

16. Technical Correction for Split (or Shared) Critical Care Services

In the CY 2022 PFS final rule, starting at 86 FR 65159, we finalized a number of billing policies for critical care CPT codes 99291 *(Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes)* and 99292 *(each additional 30 minutes).* At 86 FR 65162, we stated in error, ''Similar to our proposal for split (or shared) prolonged visits, the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, the billing practitioner could report one or more units of CPT code 99292.'' We intended to state that CPT code 99292 could be billed after 104, not 75, or more cumulative total minutes were spent providing critical care. As correctly stated elsewhere in the CY 2022 PFS final rule (regarding critical care furnished by single physicians at 86 FR 65160, and regarding concurrent care furnished by multiple practitioners in the same group and the same specialty to the same patient at 86 FR 65162), our policy is that CPT code 99291 is reportable for the first 30–74 minutes of critical care services furnished to a patient on a given date. CPT code 99292 is reportable for additional, complete 30-minute time increments furnished to the same patient (74 + 30 = 104 minutes). We clarify that our policy is the same for critical care whether the patient is receiving care from one physician, multiple practitioners in the same group and specialty who are providing concurrent care, or physicians and NPPs who are billing critical care as a split (or shared) visit.

G. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in Frontier States (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which has been extended by many successive amendments to the statute. The 1.0 floor for the work GPCI under section 1848(e)(1)(E) of the Act was most recently extended by section 101 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260, enacted December 27, 2020) through CY 2023 (that is, for services furnished no later than December 31, 2023). Therefore, the proposed CY 2023 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, reflected in the CY 2023 proposed GPCIs.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next

adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since more than 1 year has passed since the previous GPCI update was implemented in CY 2020 and 2021, we are proposing to phase in ½ of the proposed GPCI adjustment in CY 2023 and the remaining ½ of the adjustment for CY 2024.

We have completed our review of the GPCIs and are proposing new GPCIs beginning for CY 2023 in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS locality's proposed work, PE and MP expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are a useful metric for purposes of comparing overall costs and payments across fee schedule areas. The actual effect of GPCIs on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those reflected in the GAF.

As noted above, section 101 of the Consolidated Appropriations Act of 2021 extended the 1.0 work GPCI floor for services furnished through December 31, 2023. Therefore, the proposed CY 2023 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, reflected in the CY 2023 proposed GPCIs. See Addenda D and E to this proposed rule for the CY 2023 proposed GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89, and increased the number of Statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. The current 112 payment localities include 34 Statewide areas (that is, only one locality for the entire State) and 75 localities in the other 16 States, with 10 States having two localities, two States having three localities, one State having four localities, and three States having five or more localities. The remainder of the 112 PFS payment localities are comprised as follows: the combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 112 fee schedule areas, also referred to as payment localities, are defined alternatively by State boundaries (Statewide areas for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-State areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate geographically adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a State. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). The changes to the proposed CY 2023 GPCIs for each locality reflect the updated resource cost data in each area to better adjust PFS payments for geographic cost differences compared to national average costs. We note that the changes in the proposed GPCIs reflect the statutory floors and limitations on variation discussed above that may advantage some rural localities. We describe the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2023 GPCI update is available in an interim report, ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more

recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs; for the CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs; and for the CY 2020 GPCI update, we used updated BLS data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the CY 2023 GPCI update, we used updated BLS OES data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the proposed work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2020), we used 2014 through 2017 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2023 GPCI update, we used updated BLS OES data (2017 through 2020) as a replacement for the 2014 through 2017 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI.

In calculating the proposed CY 2023 GPCI update for the office rent index component of the PE GPCI, we used the 2015 through 2019 American Community Survey (ACS) 5-year estimates as a replacement for the 2013 through 2017 ACS data. The 2016 through 2020 5-year estimates were supposed to be released in December 2021, but the release date was delayed to March 17, 2022. Therefore, the recent 2015 through 2019 5-year estimates, which preceded any COVID–19 impacts, were used in the CY 2023 GPCI update, rather than the 2016 through 2020 ACS data, which were not publicly released in time for the development of this proposed rule. The Census Bureau noted that COVID–19 impacted data collection for the 2020 ACS, and the resulting challenges have the potential to affect the quality of the data. In particular, the Census Bureau noted that there were lower response rates, and nonresponse bias was found in the data collected for 2020.[71] We will analyze the ACS data collected in 2020 and subsequent years that occurred during the COVID–19 pandemic, and consider using those data for the next GPCI update after we better understand their integrity and validity for our purposes. Because the office rent index is based on 5-year estimates, we expect minimal impact from the non-response bias in the CY 2020 data on the next GPCI update, but we will examine the subsequent years' ACS data that could be similarly impacted by conditions during the COVID–19 pandemic. Because the 2020 ACS data were not released in time for us to use them in the development of this proposed rule, and the public would not have an opportunity to comment on the use of those data if we were to adjust our proposed GPCIs in the final rule to reflect the 2020 ACS data, we will not consider using the 2020 ACS data for the CY 2023 final GPCIs.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). To ensure that premium data are homogenous and comparable across geographic areas, data were collected for policies with uniform coverage limits of $1 million per occurrence and $3 million aggregate ($1 million/$3 million). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million/$3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2020 GPCI update, we used premium data presumed in effect as of December 10, 2017. The proposed CY 2023 MP GPCI update reflects premium data presumed in effect no later than December 31, 2020. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017, and refer readers to the CY 2017 PFS final rule (81 FR 80270) for additional discussion of those.

d. GPCI Cost Share Weights

For the CY 2023 GPCIs, we are proposing to continue to use the current 2006-based MEI cost share weights for

[71] *https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.*

determining the proposed PE GPCI values. Specifically, we use the cost share weights to weight the four components of the PE GPCI: employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses, as shown in Table 22. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017 and CY 2020 GPCI updates.

We note that we are proposing to rebase and revise the MEI cost share weights for CY 2023, and we refer readers to the detailed discussion in section II.M. of this proposed rule, but we are proposing to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 GPCIs, thus delaying the implementation of the rebased and revised MEI cost share weights for this purpose. We refer readers to our discussion about using the proposed rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and for the purposes of updating the GPCIs for CY 2023 in sections II.B. and VII. of this proposed rule. In those sections, we discuss our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have on PFS payments. We have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI, which was most recently done for CY 2014 (78 FR 74382 through 74383). However, in light of the overall impacts of making this change and in the interest of maintaining stability in payments, we are proposing to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 proposed PE GPCIs. We believe that doing so will allow interested parties the opportunity to review and comment on the proposed rebased and revised MEI cost share weights discussed in section II.M. of this proposed rule and their potential impacts before we actually use such rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and updating the GPCIs. This approach would maintain consistency in the data used to update both the GPCI and PFS ratesetting inputs for CY 2023; delaying implementation of the rebased and revised MEI cost share weights is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to section VII. of this proposed rule for additional discussion on this issue and impacts as it relates to PFS ratesetting and the GPCI update for CY 2023. We also refer readers to the comment solicitation in section II.B. of this proposed rule, where we discuss our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. In addition, we direct readers to the CY 2011 PFS final rule (75 FR 73256) where we similarly delayed implementation of updated MEI cost share weights in response to commenters' concerns about ongoing analysis that would inform future GPCI changes and the reallocation of labor-related costs from the medical equipment and supplies and miscellaneous component to the employee compensation component of the PE GPCI.

In the CY 2011 PFS final rule (75 FR 73256), we acknowledged that we typically update the GPCI cost share weights concurrently with the most recent MEI rebasing and revision, but in consideration of the commenters' concerns in response to the proposed rule, we did not use the revised cost share weights for the CY 2011 GPCIs and instead finalized the implementation of the rebased and revised MEI cost share weights through subsequent rulemaking. We invite comments on the delay in implementation of the MEI cost share weights for purposes of the CY 2023 GPCIs and PFS ratesetting, given the impacts discussed in section VII. of this proposed rule. We are also soliciting comments on how best to proceed with implementation of the rebased and revised MEI cost share weights in the future. More specifically, we are seeking comment on how best to incorporate the MEI cost share weights into the PE GPCI if we were to implement them outside the statutorily required triennial update in which we phase in all aspects of the GPCI update through the previously discussed 2-year (½ in each year) phase-in required by section 1848(e)(1)(C) of the Act. Section 1848(e)(1)(C) of the Act requires that, if more than one year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, specifically, we are soliciting comment on potentially incorporating the rebased and revised MEI cost share weights into the CY 2024 GPCIs. Notably, we would not be required by statute to phase in the adjustment over 2 years as specified in section 1848(e)(1)(C) of the Act because, in CY 2024, no more than one year would have elapsed since the last GPCI adjustment. Therefore, we are also seeking comment on whether it would be appropriate to use a multi-year transition to incorporate the rebased and revised MEI cost share weights for purposes of the PE GPCI and PFS ratesetting as we have done in the past when incorporating other new data into the PFS payment methodology (for example, the clinical labor update), or if, because the MEI cost share weights only impact the composition of the PE GPCI, such a transition would not be warranted. If we were to instead apply the rebased and revised MEI cost share weights for purposes of the PE GPCI and PFS ratesetting for CY 2025 or later, we would be required under section 1848(e)(1)(C) of the Act to phase in the GPCI adjustments over 2 years. We are seeking comments on whether, in that case, it would be appropriate to similarly apply a transition to implement the MEI cost share weights for purposes of PFS ratesetting as well, and refer readers to section II.B and VII. of this proposed rule for more discussion regarding the alternatives considered and impacts of a phase-in of the rebased and revised MEI cost share weights in PFS ratesetting. The proposed CY 2023 GPCI cost share weights are displayed in Table 19. We note that the proposed rebased and revised cost share weights discussed in detail in section II.M. of this proposed rule are also displayed in Table 19 for awareness and for comment solicitations regarding potential future rulemaking and GPCI updates.

TABLE 19: Proposed GPCI Cost Share Weights for CY 2023

Expense Category	Current Cost Share Weights	Proposed CY 2023 Cost Share Weights	Rebased and Revised Cost Share Weights as Proposed in Section II.M.
Work	50.866%	50.866%	47.261%
Practice Expense	44.839%	44.839%	51.341%
- Employee Compensation	16.553%	16.553%	24.716%
- Office Rent	10.223%	10.223%	5.893%%
- Purchased Services	8.095%	8.095%	13.914%
- Equipment, Supplies, Other	9.968%	9.968%	6.819%
Malpractice Insurance	4.295%	4.295%	1.398%
Total	**100.000%**	**100.000%**	**100.000%**

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in Frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be Frontier States. In general, a Frontier State is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a Frontier State, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the States identified as Frontier States for the CY 2023 PFS proposed rule. The qualifying States are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we will apply a 1.0 PE GPCI floor for these States in CY 2023.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-State fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-State locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-State locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for

transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

(1) Proposed refinement to number of unique fee schedule areas in California.

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers, and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. This refinement would ultimately change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. In light of the foregoing, for CY 2023 we are proposing to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we are proposing to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). We note that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we need to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. We are seeking comment on the proposed technical refinements to consolidate unique fee schedule areas and their locality numbers in California where the unique localities are not operationally necessary. We note that these changes, if finalized, would not have any payment implications under the PFS.

h. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of this proposed rule, we identified four technical refinements to the methodology that we are proposing because they would yield improvements over the current method; these refinements are applicable to the work and MP GPCIs, the employee wage index component of the PE GPCI, and the GAFs.

We conducted a thorough review of the BLS OES occupation codes within each of the seven occupation groups used in past updates to track and document the changes over time. As new BLS OES data are released, the availability of specific occupation codes is subject to change, and it is possible that new codes can be added, changed, or removed over time; therefore, we believe it is important to periodically review and update the occupation groups and codes based on our review during the GPCI updates. We reviewed the occupation codes and groups used to capture geographic variation in professional wages to assess other potential codes and groups that could be used in addition to the current selections to calculate the work GPCI, with significant consideration given to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). Based on our review, we are proposing the addition of two new occupation groups (and their corresponding occupation codes), Management Occupations and Business and Financial Operation Occupations, to the preexisting seven occupation groups for CY 2023, as shown in Table 20.

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TABLE 20: Additional Occupation Codes in New Occupation Groups Proposed for Inclusion in CY 2023 GPCI Update

Occupation Group	Occupation Code	Occupation Title
11-0000 Management Occupation Group	11-1011	Chief Executives
	11-1021	General and Operations Managers
	11-2011	Advertising and Promotions Managers
	11-2021	Marketing Managers
	11-2022	Sales Managers
	11-2031	Public Relations and Fundraising Managers
	11-3011	Administrative Services Managers
	11-3021	Computer and Information Systems Managers
	11-3031	Financial Managers
	11-3051	Industrial Production Managers
	11-3061	Purchasing Managers
	11-3111	Compensation and Benefits Managers
	11-3121	Human Resources Managers
	11-3131	Training and Development Managers
	11-9021	Construction Managers
	11-9031	Education Administrators, Preschool and Childcare Center/Program
	11-9032	Education Administrators, Elementary and Secondary School
	11-9033	Education Administrators, Postsecondary
	11-9039	Education Administrators, All Other
	11-9041	Architectural and Engineering Managers
	11-9111	Medical and Health Services Managers
	11-9121	Natural Sciences Managers
	11-9151	Social and Community Service Managers
	11-9161	Emergency Management Directors
	11-9199	Managers, All Other
13-0000 Business and Financial Operations Group	13-1011	Agents and Business Managers of Artists, Performers, and Athletes
	13-1021	Buyers and Purchasing Agents, Farm Products
	13-1022	Wholesale and Retail Buyers, Except Farm Products
	13-1023	Purchasing Agents, Except Wholesale, Retail, and Farm Products
	13-1041	Compliance Officers
	13-1051	Cost Estimators
	13-1071	Human Resources Specialists
	13-1075	Labor Relations Specialists
	13-1081	Logisticians
	13-1111	Management Analysts
	13-1121	Meeting, Convention, and Event Planners
	13-1131	Fundraisers
	13-1141	Compensation, Benefits, and Job Analysis Specialists
	13-1151	Training and Development Specialists
	13-1161	Market Research Analysts and Marketing Specialists
	13-1199	Business Operations Specialists, All Other
	13-2011	Accountants and Auditors
	13-2021	Appraisers and Assessors of Real Estate
	13-2031	Budget Analysts
	13-2041	Credit Analysts
	13-2051	Financial Analysts
	13-2052	Personal Financial Advisors
	13-2053	Insurance Underwriters
	13-2061	Financial Examiners
	13-2071	Credit Counselors
	13-2072	Loan Officers
	13-2081	Tax Examiners and Collectors, and Revenue Agents
	13-2099	Financial Specialists, All Other

We are also proposing to add four occupation codes to the Computer, Mathematical, Life, and Physical Science group, and three occupation codes to the Social Science, Community and Social Service, and Legal group, for

CY 2023, as shown in Table 21. The practical effect of the proposed inclusion of these occupation groups and codes on the work GPCI would be minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but their inclusion adds meaningful data regarding the geographic variation in professional wages for CY 2023.

TABLE 21: Additional Occupation Codes in Current Occupation Groups Proposed for Inclusion in CY 2023 GPCI Update

Occupation Code	Occupation Title	Common Education Requirement
Group: Computer, Mathematical, Life, and Physical Science		
15-1212	Information Security Analysts	Bachelor degree in a computer- or technology-related field
15-1257	Web Developers and Digital Interface Designers	Sometimes a two-year associate degree, other times a bachelor degree in computer science, programming, or a related field
15-1241	Computer Network Architects	Bachelor degree in computer science, information systems, engineering or related field; sometimes MBA in information systems
19-1099	Life Scientists, All Other	Bachelor's degree in a life science such as biology, chemistry, or genetics
Group: Social Science, Community and Social Service, and Legal		
19-5011	Occupational Health and Safety Specialists	Bachelor's degree
21-1099	Community and Social Service Specialists, All Other	Bachelor's degree, along with coursework in social or behavioral science
23-1012	Judicial Law Clerks	Recent law school graduates, generally, law clerks possess a master's degree in law, a specialized legal master's degree (e.g., public policy or international law), or a Juris Doctor degree

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We are proposing to modify the list of occupation codes used within the first PE GPCI component, Employee Wages, to conform more closely to the clinical labor categories used in PFS ratesetting. Specifically, six occupation codes listed as sources for clinical labor rates used to establish practice expense RVUs in PFS ratesetting that were previously inadvertently excluded in the Employee Wage Index calculation are now included in the proposed CY 2023 Employee Wage Index (29–1126, 29–1124, 19–3031, 29–1031, 29–1181, 29–1127). Lastly, we are proposing a technical refinement to the method used to calculate each locality's GAF. The GAFs are calculated as the weighted average of the three GPCIs (work, PE, and MP), essentially representing the net geographic adjustment that would be made to a theoretical standard service. Instead of the 2006-based MEI cost share weights, which were used to calculate GAFs in previous updates to the GPCIs, we calculated the CY 2023 GAFs using weights that reflect the share of total RVUs that each component (work, PE, and MP) accounts for, based on Medicare utilization data from CY 2020. The GAFs are not used for payment under the PFS but are a useful measure to illustrate the overall effect of geographic adjustments under the PFS across Medicare fee schedule areas. We believe that using the share of RVUs reflected in recent Medicare utilization data as weights when calculating the CY 2023 GAFs results in GAFs that more accurately reflect the composite effect of geographic adjustment on payment, year over year, as compared to the GAFs calculated using the 2006-based MEI cost share weights. This change also allows the use of current Medicare utilization data that are available each year as opposed to the MEI cost share weights that are not updated as frequently. The proposed weights used to calculate the CY 2023 GAFs are displayed in Table 22.

TABLE 22: Weights Used to Calculate the CY 2023 GAFs

Component to Be Weighted	Current Weights (2006-based MEI Cost Share Weights)	CY 2023 Proposed Weights (CY 2020 Utilization Shares)
Work	50.866%	50.247%
Practice Expense	44.839%	45.556%
Malpractice Insurance	4.295%	4.196%

These four proposed methodological refinements, including changes to: (1) the occupation group; (2) occupation codes; (3) occupation codes used for the Employee Wage Index; and (4) the GAF weighting adjustment, will yield improved mathematical precision in the proposed CY 2023 GPCIs and GAFs by providing for a more accurate, full

landscape of occupations that should be accounted for in the work and PE GPCIs, and by aligning the GAF equation weights to use routinely available data Additional information on the GPCI methodology and the proposed refinements are available in the interim report, ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS'' on our website located under the supporting documents section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

i. Alternatives Considered Related to the Use of the American Community Survey (ACS) Data for Office Rent Index

Commenters often express concern about the use of residential rents as a proxy for physician office space costs for purposes of updating the PE GPCIs, and state that CMS should collect commercial rent data and use it either as the basis for measuring geographic differences in physician office rents, or if this is not feasible, use it to validate the residential rents as a proxy for physician office rents. In the past, commenters have requested that CMS provide a specific explanation of the barriers to obtaining better commercial rent data and that we reevaluate existing databases to find or develop a nationwide measure of commercial office rents for use in calculating PE GPCIs. For each GPCI update, we have noted that our efforts are ongoing to identify a publicly-available, robust, nationally representative commercial rent data source that could be made available to CMS for this purpose. We have welcomed opportunities to discuss such data sources with impacted parties and to incorporate such data, as appropriate in the GPCI calculation process, through our annual rulemaking process.

Because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires us to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data source that is available on a nationwide basis, that is regularly updated, and retains consistency area-to-area, year-to-year. The ACS is administered by the United States Census Bureau, which is a leading source of national, robust, high quality, publicly available data. We agree that a data source for commercial office rents that provided for adequate representation of urban and rural areas nationally would be preferable to a residential rent data source as a proxy for commercial rents. We have previously discussed in the CY 2005, CY 2008, CY 2011, and CY 2017 (69 FR 66262, 72 FR 66376, 75 FR 73257, and 81 FR 80265, respectively) final rules that we recognize that apartment rents may not be a perfect proxy for physician office rent.

We have conducted searches for commercial rent data sources for consideration as an alternative to the ACS data in the past and have not found or received public comments with suggestions of reliable data sources that meet our needs. For CY 2023, we have conducted another search for reliable commercial rent data sources that are publicly available for the CY 2023 update and did not find any reliable data sources that would meet our needs. The principal characteristic of any substitute data source for the ACS data would be that it captures geographic variation in the office space cost for physician practices. We primarily investigated sources that report data on commercial real estate, but we also considered a few residential rent data sources and one data source that reports on a type of property that would be unable to house a physician practice—U.S. Post Office (P.O.) box rentals. Because the underlying property in which the P.O. boxes are located is commercial in nature, the rental rates may reflect the underlying geographic variation in facility cost. Because this source has other features that are important for creating a geographic index, we have included it for consideration. Although impacted parties may prefer a database focused on the types of properties that physicians would use for offices (that is, a commercial rent database), the identified potential data alternatives discussed below failed to meet one or more of five criteria that we believe are critical to the creation of an appropriate geographic index.

We used the following five criteria to analyze the potential data sources for this search: (1) applicability to planned use; (2) standardization of the measure; (3) potential bias; (4) geographic scope, distribution, and granularity of the data; and (5) availability, continuity, and price of the data. Our review revealed challenges with the commercial real estate market data in several of these criteria. Under the first criterion, there are two sub-criteria that present problems with the type of real estate data reported when we considered their use for creating a geographic index: (1A) leases versus sales of commercial real estate, and (1B) comparables versus listings versus assessments of commercial real estate. For the first sub-criterion, the commercial and residential real estate markets can be subdivided into markets for leases and sales. Terms for commercial leased properties are often varied and not readily available. Commercial sales, especially of office condominiums, may be more readily available and require less adjustment for use in a geographic index. The availability of different arrangements—leasing versus owning—may vary geographically, affecting the underlying stability and representativeness of an index based on either. Under the second sub-criterion, an important distinction is whether the data in the alternative data source represents closed transactions (known as ''comparables'' or ''comps'') or asking prices (known as ''listings''), regardless of whether the source is reporting data for leased or sales of commercial property. Because asking prices are often aspirational, professional real estate appraisers rely on comparable transactions in order to estimate a price for sale or lease. Therefore, comparables provide the most reliable substitute dataset for consideration for use in creating a geographic index. Assessments are the estimated values of real property set by the tax assessors in each State, which are generally intended to reflect full cash value of the property, though there may be State-specific laws and regulations that interfere (that is, by limiting the percentage increase in a property from year to year if it has not been transferred). Assessments for commercial properties often rely heavily on the ''income method'' of valuation, which capitalizes the net income the property does or could receive if rented. The advantage of assessments for use in creation of a geographic index is their existence for every property in the United States.

The second criterion is that appropriate adjustments need to be made to reduce variation for other factors, or the standardization of the data reported by a considered alternative data source. The primary data adjustment is to standardize the size of the property. For commercial space, conversion to a price per square foot (price/SF) value allows for direct comparison between properties. There are other factors involved in standardizing commercial rents and sale prices. The Building Owners and Managers Association (BOMA) groups buildings into three property classes:

- Class A: Most prestigious buildings competing for premiere office users with rents above market average for the area. These buildings have high quality standard finishes, state of the art building systems and amenities,

exceptional accessibility, and a definite market presence.

- Class B: Buildings competing for a wide range of users with rents in the average range for the market. Buildings finishes are good to fair for the area, and systems are adequate but the building does not compete with Class A at the same price.
- Class C: Buildings competing for tenants requiring functional space at rents below average for the market.[72]

A dataset of commercial rentals or sales must include the building class information so properties can be appropriately compared to each other, similar to the way that CMS currently only compares ACS rent data for two-bedroom apartments. For leases, the dataset would also need to specify lease type (Single Net, Double Net, Triple Net, Bondable Net, Full Service Gross, Modified Gross, and or Percentage).[73] The same property rented under a type of Net lease would be expected to have a lower rent than if it were rented under a Full-Service lease because the lessee would pay some amount towards operating expenses. Although a dataset may contain an indication of the type of lease, it may not include the amount of operating expenses paid by the lessee that would be necessary to standardize the rent or other terms that affected the final transaction price. There are often considerable privacy considerations with respect to commercial transactions in order to maintain competitive advantage, so accurate information is often difficult to obtain. Typically, the sale price for a leased property, assuming an arms-length transaction, accounts for the detailed lease terms applicable to the property and likely would not require adjustment for this factor. Another consideration is the effective date of the transaction. Market prices for leases and sales can change rapidly or slowly, and even transactions occurring within the same calendar year may or may not require adjustment in order to be reflective of the market at the intended point in time, and therefore, the transaction date is critical for professional appraisals. Markets are also localized, so even data reported for areas in relatively close proximity may not experience the same price fluctuations.

The third criterion is that potential bias is limited in a considered alternative data source. Our search to date was unable to locate any scientifically designed national survey of commercial property costs. Many of the data sources are intended to facilitate the sale of commercial property and provide listings, rather than comparables. They also may only contain a fraction of the listings on the market and have been selected by brokers to advertise for sale, rather than to represent the entire market, resulting in substantial bias. Even the most comprehensive and detailed data sources for verified transactions are designed to support valuation of individual properties. These databases reflect the mix of properties that are either currently available or have been sold or leased during a defined period. The aggregate data are not intended to produce an unbiased estimate of the average cost per square foot in a particular geographic area, whereas, the ACS is a scientifically designed and implemented national housing survey created by the U.S. Census Bureau that has been designed to reduce bias in the statistics it creates.

The fourth criterion is that the alternate data source would need to be national in scope and sufficiently granular to capture the characteristics of highly localized real estate markets. The ACS data have been consistently available in each year for the majority of counties in the nation. Although some of the commercial data sources may range nationwide and provide property-level data, there may be a much higher proportion of areas with missing data. An important consideration for the office rent index is that it sufficiently captures data in both urban and rural areas. Rural areas may have a less active commercial real estate market than urban areas, in which case there may be few transactions to use in a geographic index.

Lastly, the fifth criterion is that the data source be publicly available, consistently available for CMS' GPCI update years, and/or reasonably priced in order to facilitate transparency and administrative efficiency. Proprietary databases can only be accessed by those who sign up for the service, and use of the data is governed by Terms of Service (TOS) that may preclude its use in derivative works, such as the creation of a geographic index, or dissemination of the data. Public databases are more likely to be accessible and able to be used for derivative work, such as the creation of the GPCIs. Any change in the data source we use in the creation of the index is likely to cause changes in index values, and possibly invoke critique if the resulting changes are significant. If CMS were to consider a change in data source, the change would need to be sustainable over time, and therefore, the data must be consistently accessible for subsequent GPCI updates, and data sources must maintain consistency over time in order to avoid any potential dramatic changes and/or the need to refine the adjustments to a dataset each update year, which would introduce unnecessary variation in the index. If the data source changes or discontinues the dataset, CMS would need to find a replacement data source, possibly within a short time period. This would likely introduce the possibility of dramatic changes and variation in the index that does not reflect the real geographic changes between update years—stemming from the use of different data sources. Additionally, the price to obtain and make necessary adjustments to the data discussed above may be prohibitive for use in the GPCIs.

The Federal Government already paid for the construction of the ACS, the ACS provides the data in a very usable form, CMS can consistently and freely access the data, and relatively minor processing is required to turn it into an index. Every proprietary database is likely to charge substantial amounts to access the data as it is currently provided, which will be geared to uses very different from the creation of an office rent index. There may be substantial work required to gather and process the data and TOS conditions imposed by the database owners may not allow even free data to be used for the intended purpose. In all cases, it is likely that CMS would need to negotiate the terms for utilizing any proprietary sources.

We identified eight data sources for analysis as potential alternatives to the ACS, but all failed to meet one or more of the five key criteria discussed above that would allow us to better reflect geographic cost variation for the office rent component of the PE GPCI that is currently measured using the ACS. We specifically identified the following potential data sources: (1) REIS® Real Estate Solutions by Moody's Analytics®; (2) CompStak; (3) CoStar™; (4) Zillow® Assessor and Real Estate Database (ZTRAX); (5) U.S. Postal Service (USPS®) P.O. Box Rental; (6) GSA® Lease Inventory; (7) Reonomy®; and (8) SMR Research. Three of the eight data sources had substantial costs associated with obtaining the data, and we were unable to obtain pricing information for an additional two of the eight without extensive discussions with a sales representative. Two of the eight sources lacked necessary building class information, and many of the eight sources presented challenges with TOS restrictions, representativeness of rural

[72] *https://www.boma.org/BOMA/Research-Resources/Industry_Resources/BuildingClassDefinitions.aspx.*

[73] *https://www.reonomy.com/blog/post/commercial-lease-types.*

areas, small or undisclosed sample sizes, sample sizes that differed from year to year, and/or a large number of geographic areas with missing data.

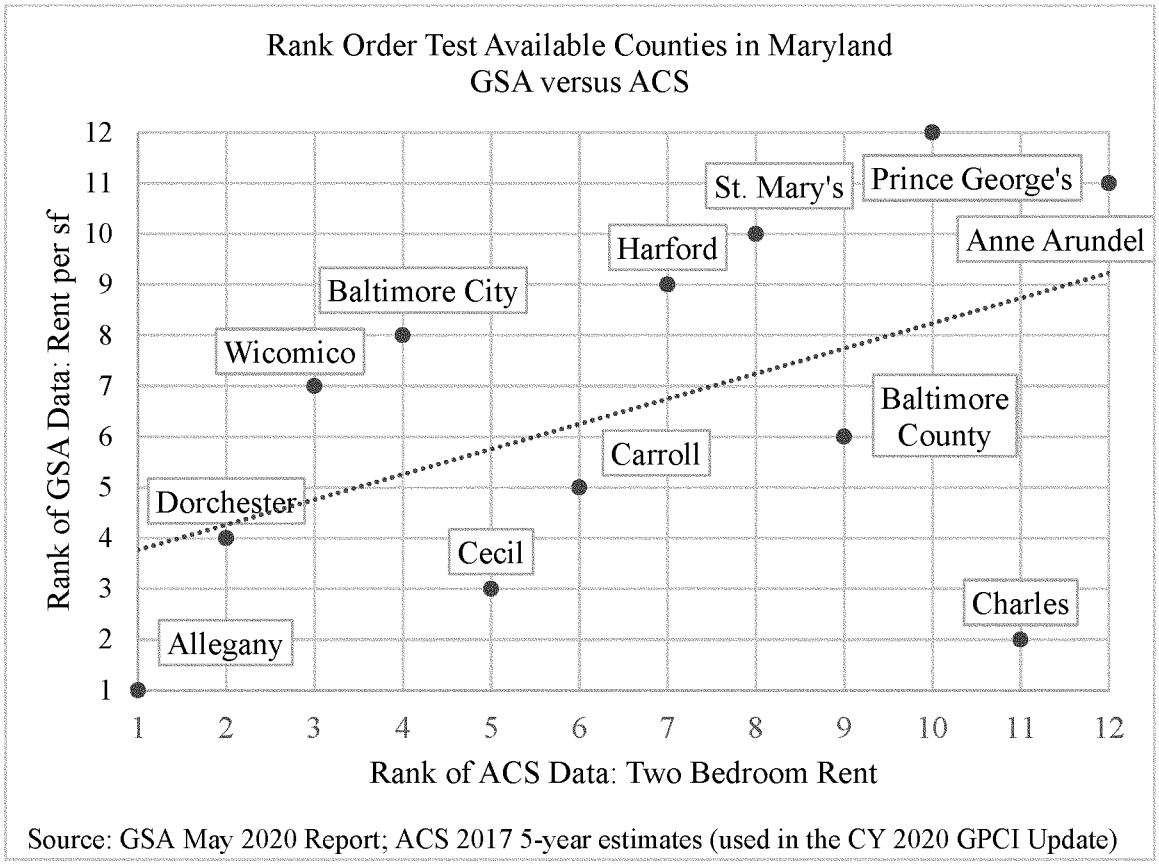
While we determined that none of these data sources are appropriate substitutes for the ACS data we currently use, based on their failure to meet one or more of the five key criteria discussed above, some of the sources possess useful qualities that allowed for further preliminary research into the correlation between commercial and residential rent that fell within the confines of our contractual restrictions. To investigate whether the use of ASC residential rents captures geographic variation in office rents, as discussed above, we identified a few data alternatives above for further research and examined their correlation with the ACS residential rent data in effort to evaluate the validity of the ACS data as a proxy for determining geographic variation in office rents. Overall, our ongoing analysis shows that the ACS residential rent data are highly correlated with commercial rents across areas. Therefore, we have concluded that the continued use of the ACS data for the office rent component of the PE GPCI is appropriate. We considered the use of USPS P.O. Box Rental data for preliminary analysis, as it is free, publicly available, and national in scope (in all zip codes where P.O. Boxes are available), but resource and time constraints limited us from considering this for the CY 2023 update. P.O. Box rent data is available online, but it is not formatted in an easy-to-use dataset that we could readily analyze without conducting resource-intensive data extraction and preparation. Considering that the P.O. Box rent data would have required significant resources, and that expending such resources was not feasible for the CY 2023 proposed rule, we identified the GSA Lease Inventory data source as the next best alternative data source to use to evaluate the correlation between residential and commercial rents because it is publicly available, free, and accessible in an easy-to-use format that required limited adjustments to allow analysis. To get a comparative sense of the rents per square foot that would be suggested for a specific geographic area, we chose to compare the GSA Lease Inventory data and the ACS data for available counties in the State of Maryland. As shown in Table 23, the GSA Lease Inventory data are missing for approximately half of the counties in Maryland. For those counties with available GSA data, the rent per square foot of the GSA leased facilities is shown in Table 23 and can be compared to the corresponding ACS residential rent data for that county.

TABLE 23: Comparing GSA Lease Inventory and ACS Data for Counties in Maryland

		GSA Data				ACS Data		
County	**Population**	**Freq**	**Rent per sf ($)**	**Unweighted Index**	**Population Weighted Index**	**Two Bedroom Rent ($)**	**Unweighted Index**	**Population Weighted Index**
Allegany	73,060	4	17.54	0.651	0.540	670	0.588	0.532
Anne Arundel	559,737	23	32.98	1.224	1.015	1,543	1.354	1.225
Baltimore City	621,000	29	27.63	1.025	0.850	1,053	0.924	0.836
Baltimore County	825,666	18	24.44	0.907	0.752	1,233	1.082	0.979
Carroll	167,535	3	24.28	0.901	0.747	1,102	0.967	0.875
Cecil	102,175	3	19.98	0.742	0.615	1,062	0.932	0.843
Charles	154,357	1	18.70	0.694	0.575	1,487	1.305	1.180
Dorchester	32,451	3	22.37	0.830	0.688	828	0.727	0.657
Harford	249,776	5	28.05	1.041	0.863	1,152	1.011	0.914
Prince George's	897,693	52	52.36	1.944	1.610	1,401	1.229	1.112
St Marys	110,675	3	29.58	1.098	0.910	1,174	1.030	0.932
Wicomico	101,527	8	25.35	0.941	0.780	970	0.851	0.770
Garrett	29,677	Not available in GSA Lease Inventory data				596	n/a	n/a
Somerset	25,899					687	n/a	n/a
Caroline	32,653					849	n/a	n/a
Washington	149,571					856	n/a	n/a
Worcester	51,441					920	n/a	n/a
Kent	19,819					927	n/a	n/a
Talbot	37,668					1,071	n/a	n/a
Frederick	243,465					1,277	n/a	n/a
Queen Anne's	48,712					1,290	n/a	n/a
Calvert	90,527					1,321	n/a	n/a
Howard	308,447					1,686	n/a	n/a
Montgomery	1,026,371					1,711	n/a	n/a
Unweighted Average			**26.94**	**1.000**		**1,140**	**1.000**	
Weighted Average			**32.51**		**1.000**	**1,260**		**1.000**

Figure 1 shows a rank order test for the counties in Maryland where both GSA Lease Inventory data and ACS data are available. Allegany County has the lowest rent per square foot in the GSA Lease Inventory data and the lowest residential rent in the ACS data. Anne Arundel County has the highest residential rent data and the second highest GSA Lease Inventory data. Analysis shows that the rank order of the available counties in the GSA Lease Inventory data follow a relatively similar pattern (positive, linear relationship) to the same counties in the ACS data.

FIGURE 1: Rank Order Test for Counties with Both GSA and ACS Data in Maryland



Source: GSA May 2020 Report; ACS 2017 5-year estimates (used in the CY 2020 GPCI Update)

We expanded the comparison of the GSA Lease Inventory data with the ACS residential rent data from available counties in Maryland to all available counties nationwide by creating a rent per square foot measure for all GSA Lease Inventory records using the January 2017 GSA Leased Inventory data. The comparison was done by condensing the GSA Lease data to the county level, merging it with the ACS data (for counties where GSA data were available), and aggregating it to the Medicare locality level, weighting by county population. We performed two rank order tests for both ACS (median two-bedroom rent) and GSA (rent per SF) measures in all available localities where at least 50 percent, and 75 percent, subsequently, of the locality population was represented in the county-level GSA data file. Similar to our findings from the initial analysis of Maryland counties, the expanded comparisons generally show a positive, linear relationship between rank of ACS (median two-bedroom rent) and rank of GSA (rent per SF) measures. Because the GSA Lease Inventory data are not geographically complete, our analyses were limited. GSA Lease Inventory data are sparse or nonexistent in some counties, therefore, we calculated the percent of the locality population and only included localities in our analysis with county-level data where at least 50 percent (and 75 percent for the second analysis) of the locality population was represented in the county-level GSA data file. For example, Locality A includes county 1 and county 2. If the GSA data includes county 1 (with a population of 1,000), but not county 2 (population of 50), we included Locality A in the analysis, as it met the 50 percent and 75 percent thresholds. In contrast, if the GSA data includes county 2 (population of 50), but not county 1 (population of 1,000), we did not perform analysis on Locality A. The January 2017 GSA data file includes information on approximately 8,200 GSA leases across the country, which were then aggregated to the county level, and then to the Medicare locality level for our analysis. After these two aggregations, we had enough GSA Lease Inventory data to perform two rank order tests on 52 Medicare localities, one rank order test for counties where at least 50 percent of the locality population was represented and a second rank order test for counties where 75 percent of the locality population was represented. We further analyzed the outlier localities (where the ACS rank differs from the GSA rank by ±30 ranks) and found that when the population threshold increased from 50 percent to 75 percent, we see a reduction in outliers from 13 to only two localities, indicating that more

complete data (that is, 75 percent of the locality population represented in GSA lease data) yields higher correlation between the median two-bedroom rent in the ACS data and the rent per square foot in the GSA data. This correlative effect supports the continued use of ACS data in the GPCI update for CY 2023, as it indicates that GSA lease data (a commercial rent data source) and ACS residential rents varied similarly across geographic areas.

It is important to note that we use the ACS data to create an index to measure cost differences, and not as a direct proxy for commercial office rents. Rather, the ACS data are used to measure geographic variation in residential rents, which is used as a proxy for the geographic variation in commercial office rent. Based on our limited analyses comparing the GSA and ACS data, which showed that commercial and residential rents varied similarly across geographic areas, and the lack of any identified alternative data source that meets all five of the criteria discussed above, we believe that it is appropriate to continue use of the ACS data.

With regard to the suggestion that CMS should collect commercial rent data, we note that we discussed this issue in the CY 2012 PFS final rule with comment period (76 FR 73088) and stated that the development and implementation of a survey could take several years if CMS were to survey physicians directly to gather data to compute the office rent index. Additionally, we have historically not sought direct survey data from physicians related to the GPCI to avoid issues of circularity and self-reporting bias. In the CY 2011 PFS final rule with comment period (75 FR 73259), we solicited public comments regarding the benefits of utilizing physician cost reports to potentially achieve greater precision in measuring the relative cost difference among Medicare localities. We also asked for comments regarding the administrative burden of requiring physicians to routinely complete these cost reports and whether this should be mandatory for physicians' practices. We did not receive any feedback related to that comment solicitation during the open public comment period for the CY 2011 PFS final rule with comment period.

We reiterate that the GPCIs are not an absolute measure of practice costs. Rather they are a measure of the relative cost differences for each of the three GPCI components. The U.S. Census Bureau is a Federal agency that specializes in data collection, accuracy, and reliability, and we continue to believe that where such a publicly available resource exists that can provide useful data to assess geographic cost differences in office rent, even though it is a proxy for the exact data we seek, that we should utilize that available resource. In addition to reviewing alternative data sources, we also explored whether there are alternative ways of using the ACS data that could improve geographic representation or improve impacted parties' confidence in it as a reasonable way to capture geographic variation in office rent, including consideration of alternative ways to handle counties where we are missing ACS data, as well as using alternative variables within the ACS data to assess whether there are other similar variables that have more complete data than median gross rent for two-bedroom residences. Our research indicates that using alternatives within the ACS would likely result in minimal changes to the resulting index and would likely not address commenters' concerns regarding use of residential rent data as a proxy for office rent. Our research also suggests that the variation captured by the two-bedroom measure is highly correlated with the geographic variation in one-bedroom and three-bedroom units. The high correlation coefficient strengthens the support for using the ACS two-bedroom measure to capture office rent variation across areas. We explored the continued use of the ACS data to see if there are other available variables that have a lower count of missing observations. The data includes variables on the median gross rent for no bedrooms, one bedroom, two bedrooms, three bedrooms, four bedrooms, five or more bedrooms, and the total median gross rent. Table 24 shows the number of observations that are missing for each of the median gross rent variables in the 2017 5-year ACS data.

TABLE 24: Number of Missing Observations for ACS Residential Rent Variables

Total Number of Missing Observations	Frequency	Percent
Median gross rent -- - Total:	1	0.03
Median gross rent -- - Total: - No bedroom	1310	40.68
Median gross rent -- - Total: - 1 bedroom	164	5.09
Median gross rent -- - Total: - 2 bedrooms	31	0.96
Median gross rent -- - Total: - 3 bedrooms	21	0.65
Median gross rent -- - Total: - 4 bedrooms	367	11.4
Median gross rent -- - Total: - 5 or more bedrooms	1553	48.23

Source: 2017 ACS 5-Year Estimates

Based on the 2017 5-year ACS data, total median gross rent and median gross rent for three bedrooms are two available alternative variables that have fewer missing county-level ACS data than the currently used median gross rent for two bedrooms. However, it is important to note that the number of missing observations for each variable could change over time. While the median gross rent for two bedrooms has a relatively low count for missing observations, it could be substituted with the total median gross rent, which has the smallest count of missing observations. In future years of ACS data, there could be more or fewer missing observations for this list of variables. Moving to use of the median gross rent for three bedrooms would result in slightly fewer missing observations in the 2017 ACS 5-Year Estimates, but this may not be the case for all update years.

There are also alternative ways of handling counties that are missing data. In the CY 2020 update, we imputed county-level rent estimates using the average value for a given county's MSA. Other options include using the average value for contiguous counties, using an average value for the county's State or removing the missing observation from

the calculation. However, we note that the current method of handling counties that are missing data is a reasonable approach and any alternative would not likely affect the calculation materially. Additionally, since there are so few counties that are missing data (less than one percent), these alternatives (even if we had reason to prefer one of them) would likely have no impact on the resulting index. Table 25 shows the correlation coefficients between the available residential rent variables in the ACS. The variation captured by the two-bedroom measure is highly correlated with the geographic variation in one-bedroom and three-bedroom units (approximately 0.9). This relationship is similar, but not quite as prominent for the other residential measures. The correlation coefficient between three-bedroom and four-bedroom rent measures is also approximately 0.9. Based on our research, the geographic variation in residential rents is consistent regardless of specific measure used, and therefore, a change in the ACS variable used or a change in the way of handling counties that are missing data would likely result in minimal changes to the resulting index.

TABLE 25: Correlation Coefficient Between ACS Residential Rent Variables

ACS Residential Rent Variables	Correlation Coefficient	N (max 3,220)
0 vs. 1 bedroom	0.55	1,895
1 vs. 2 bedrooms	0.89	3,043
2 vs. 3 bedrooms	0.92	3,172
3 vs. 4 bedrooms	0.87	2,850
4 vs. 5 bedrooms	0.77	1,645
Total vs. 2 bedrooms	0.95	3,189

Source: 2017 ACS 5-Year Estimates

Given its national representation, reliability, high response rate and frequent updates, and based on the rank order comparison of GSA and ACS data and high correlation coefficients for the ASC residential rent variables discussed above, we continue to believe the ACS residential rent data is the most appropriate data source available at this time for the purposes of calculating the rent index of the PE GPCI. We undertook a comprehensive analysis of alternatives to the ACS data and concluded that there is still no acceptable national data source available for physician office or other comparable commercial rents, and therefore, we propose to continue to use county-level residential rent data from the ACS as a proxy for the relative cost differences in commercial office rents for the proposed CY 2023 update, and have done so in calculating the CY 2023 proposed GPCIs.

j. Proposed GPCI Update Summary

As explained in the Background section above, section 1848(e)(1)(C) of the Act mandates the periodic review and adjustment of GPCIs. For each periodic review and adjustment, we publish the proposed GPCIs in the PFS proposed rule to provide an opportunity for public notice and comment, and allow us to consider whether any revisions in response to comments are warranted prior to implementation. The CY 2023 updated GPCIs that we propose for the first and second year of the 2-year phase-in, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our website under the supporting documents section of the CY 2023 PFS proposed rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

H. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that valuations for each service under the PFS be composed of three components: work, practice expense (PE), and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period (79 FR 67591 through 67596), we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs, see the CY 2015 PFS proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596). In the CY 2018 PFS proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors, used in the calculation of MP RVUs, prior to the next required 5-year update (CY 2020), using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however, the proposal was ultimately not finalized for CY 2018.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor (RF) was

applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. In the CY 2020 PFS final rule with comment period, we implemented the fourth review and update of MP RVUs, and we also conducted the statutorily required 3-year review of the GPCIs. For a comprehensive discussion of the fourth review and update of MP RVUs, see the CY 2020 PFS proposed rule (84 FR 40504 through 40510) and final rule with comment period (84 FR 62606 through 62615). The MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Therefore, for the CY 2020 update of MP RVUs we finalized a policy to align the update of MP premium data with the update to the MP GPCIs to increase efficiency. Effective beginning in CY 2020, our policy is to review, and if necessary update, the MP RVUs at least every 3 years, similar to our review and update of the GPCIs.

2. Methodology for the Proposed Revision of Resource-Based Malpractice (MP) RVUs

a. General Discussion

We calculated the MP RVUs that we are proposing for CY 2023 using updated MP premium data obtained from State insurance rate filings. We used a calculation methodology for the CY 2023 review and update of resource-based MP RVUs that largely parallels the process used in the CY 2020 update; however, we are proposing to incorporate some methodological refinements, which are described below. The MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors (RFs) for the various specialties that furnish a particular service. Because MP premiums vary by State and specialty, the MP premium information must be weighted geographically and by specialty. The MP RVUs that we are proposing were calculated using four data sources:

- MP premium data presumed to be in effect as of December 31, 2020;
- CY 2020 Medicare payment and utilization data;
- Higher of the CY 2022 final work RVUs or the clinical labor portion of the direct PE RVUs; and
- CY 2022 MP GPCIs.

We used the higher of the CY 2022 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2023 proposed MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2020 update, the proposed MP RVUs were calculated using specialty-specific MP premium data because they represent the expense incurred by practitioners to obtain MP insurance as reported by insurers. For CY 2023, the most current MP premium data available, with a presumed effective date of no later than December 31, 2020, were obtained from insurers with the largest market share in each State. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) market share report. This annual report provides State-level market share for entities that provide premium liability insurance (PLI) in a State. Premium data were downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating States. For non-SERFF States, data were downloaded from the State-specific website (if available online) or obtained directly from the State's alternate access to filings. For SERFF States and non-SERFF States with online access to filings, the 2020 market share report was used to select companies. These were the most current data available during the data collection and acquisition process.

MP insurance premium data were collected from all 50 States, and the District of Columbia. Efforts were made to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection, and therefore, filings from the previous update were used. Consistent with the CY 2020 update, no filings were collected for the other U.S. territories: American Samoa; Guam; Virgin Islands; or Northern Mariana Islands. MP premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. Adjustments were made to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the State's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in States where participation in such funds is mandatory.

Premium data were included for all physician and nonphysician practitioner (NPP) specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all States, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all States. In the CY 2020 PFS final rule (84 FR 62607 through 62610), we finalized methodological improvements that expanded the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

b. Proposed Methodological Refinements

For the CY 2023 update, we are proposing the following methodological improvements to the development of MP premium data:

(1) Improving our current imputation strategy to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which

sometimes use unique specialty names or do not include all CMS specialties.

In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, we finalized in the CY 2020 final rule (84 FR 62607 through 62610) to use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there were no data corresponding to a CMS specialty in the filing, we finalized a policy to use total imputation to establish premiums for that specialty. We are proposing to further refine our strategy for imputing risk factor values for specialties that have incomplete data during the data collection process by using rates mapped from the more commonly reported specialty within risk class as opposed to excluding underrepresented filing data.

For example, Hospice and Palliative Care is typically assigned the same risk class as Internal medicine. Rather than excluding Hospice and Palliative Care because there is insufficient filing data, we would use Internal Medicine rates in filings that did not explicitly report Hospice and Palliative Care. For the CY 2020 update, commenters requested that we continue to improve our data collection process to ensure that as much specialty-specific data as possible are used to calculate risk factors. Therefore, we are proposing to utilize this small improvement for collecting risk value input data in the future, as this retains as much data as possible and maps specialties more intentionally.

(2) Creation of a risk index for the calculation of MP RVUs.

We are proposing to utilize a true MP risk index as opposed to derived risk factors when calculating MP RVUs. Historically, we have used risk factors, which is a ratio of a specialty's national average premium to a single referent specialty's national average premium. This denominator has typically been based on the national average premium for the Allergy/Immunology specialty, which has had the lowest average premium for 2017 and 2020. The proposed risk index would be calculated as a ratio of the specialty's national average premium to the volume-weighted national average premium across all specialties. We believe this change will increase consistency with the calculation of MP RVUs, so that changes in the MP risk index reflect changes in payment, as opposed to changes relative only to the specialty with the lowest national average premium. We believe that this definitional change to risk index does not impact the pricing of services in the PFS since it does not change relative risk across specialties, and MP RVUs are rescaled for purposes of budget neutrality to be equal to the overall pool of MP RVUs. Readers can refer to the section of this proposed rule entitled, ''Application of BN to Adjustments of RVUs'' for a discussion of our budget neutrality process.

c. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 PFS final rule with comment period (79 FR 67591), along with the above proposed methodological improvements. The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk index of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area MP premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2015–2019 American Community Survey (ACS) 5-year estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2022 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of MP claims if they occur. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated a distinct risk index for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty. These methods are discussed below.

Developing Distinct Service Risk Groups: We determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 17 specialties (there were 15 such specialties in the CY 2020 update). These specialties are listed in Table 26. The CY 2023 update uses the same structure of specialty/service risk group as the previous update except that Unknown Physician Specialty (99) is now divided into surgery and non-surgery groups. We were able to collect an expanded amount of premium data for this specialty relative to the previous update, and this service risk group structure change is reflective of the patterns observed in the most current premium data. For all other specialties (those that are not listed in Table 26) that typically do not distinguish premiums as described above, a single risk index value was calculated, and that specialty risk index value was applied to all services performed by those specialties. For further discussion of the information contained in Table 26, refer to ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule'' Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

TABLE 26: Specialties Subdivided into Service Risk Groups

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Cardiac Electrophysiology (21), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93) Unknown Physician Specialty (99)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step (3): Calculate a risk index for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk index. These risk index values are calculated by dividing the national average premium for each specialty by the volume-weighted national average premium across all specialties. For specialties with sufficient surgical and non-surgical premium data, we calculated both a surgical and non-surgical risk index value. Similarly, for specialties with rate filings that distinguished surgical premiums with obstetrics, we recognized that service-risk subgroup of the specialty and calculated a separate surgical with obstetrics risk index value.

Table 27 shows the risk index values by specialty type and service risk group.

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TABLE 27: CY 2023 Risk Index by Specialty and Service Risk Group

Medicare Specialty Code and Name	2023 Service Risk Group	2023 Risk Index
01-General practice	NO SURG	0.703
01-General practice	SURG	1.472
01-General practice	OB	1.634
02-General surgery	ALL	2.922
03-Allergy/immunology	ALL	0.430
04-Otolaryngology	NO SURG	0.681
04-Otolaryngology	SURG	1.656
05-Anesthesiology	ALL	0.932
06-Cardiology	NO SURG	0.776
06-Cardiology	SURG	2.623
07-Dermatology	NO SURG	0.490
07-Dermatology	SURG	1.190
08-Family practice	NO SURG	0.713
08-Family practice	SURG	1.531
08-Family practice	OB	1.633
09-Interventional Pain Management	ALL	1.200
10-Gastroenterology	NO SURG	0.785
10-Gastroenterology	SURG	1.351
11-Internal medicine	ALL	0.756
12-Osteopathic manipulative therapy	ALL	0.433
13-Neurology	NO SURG	0.935
13-Neurology	SURG	4.717
14-Neurosurgery	ALL	4.717
15-Speech Language Pathology	ALL	0.011*
16-Obstetrics/gynecology	NO SURG	0.668
16-Obstetrics/gynecology	SURG	1.922
16-Obstetrics/gynecology	OB	3.479
17-Hospice & Palliative Care	ALL	0.745
18-Ophthalmology	NO SURG	0.492
18-Ophthalmology	SURG	0.893
19-Oral surgery (dental only)	ALL	1.097
20-Orthopedic surgery	ALL	2.344
21-Cardiac Electrophysiology	NO SURG	0.776
21-Cardiac Electrophysiology	SURG	2.622
22-Pathology	ALL	0.635
23-Sports Medicine	ALL	0.730
24-Plastic and reconstructive surgery	ALL	2.099
25-Physical medicine and rehabilitation	ALL	0.607
26-Psychiatry	ALL	0.459
27-Geriatric Psychiatry	ALL	0.459
28-Colorectal surgery	ALL	1.543
29-Pulmonary disease	ALL	0.895
30-Diagnostic radiology	ALL	1.009
31-Intensive Cardiac Rehab	ALL	0.776
32-Anesthesiologist assistants	ALL	0.272
33-Thoracic surgery	ALL	2.804
34-Urology	NO SURG	0.815
34-Urology	SURG	1.385
35-Chiropractic	ALL	0.147
36-Nuclear medicine	ALL	0.569
37-Pediatric medicine	ALL	0.780
38-Geriatric medicine	NO SURG	0.655
38-Geriatric medicine	SURG	1.546
39-Nephrology	NO SURG	0.683
39-Nephrology	SURG	1.160

Medicare Specialty Code and Name	2023 Service Risk Group	2023 Risk Index
40-Hand surgery	ALL	1.955
41-Optometry	ALL	0.046*
42-Certified nurse midwife	ALL	0.912
43-CRNA	ALL	0.275
44-Infectious disease	ALL	0.868
45-Mammography screening center	ALL	0.017*
46-Endocrinology	NO SURG	0.660
46-Endocrinology	SURG	1.283
47-Independent Diagnostic Testing Facility	ALL	0.017*
48-Podiatry	NO SURG	0.494
48-Podiatry	SURG	0.901
62-Psychologist	ALL	0.066*
63-Portable X-ray supplier	ALL	0.015*
64-Audiologist	ALL	0.013*
65-Physical therapist	ALL	0.034*
66-Rheumatology	ALL	0.666
67-Occupational therapist	ALL	0.018*
68-Clinical psychologist	ALL	0.068*
69-Clinical laboratory	ALL	0.017*
70-Multispecialty clinic or group practice	ALL	0.685
71-Registered Dietician/Nutrition Professional	ALL	0.264*
72-Pain management	ALL	1.184
75-Slide Preparation Facilities	ALL	0.017*
76-Peripheral vascular disease	ALL	2.826
77-Vascular surgery	ALL	2.825
78-Cardiac surgery	ALL	2.623
79-Addiction medicine	ALL	0.448
80-Licensed clinical social worker	ALL	0.023*
81-Critical care (intensivists)	ALL	1.124
82-Hematology	ALL	0.723
83-Hematology/oncology	ALL	0.741
84-Preventive medicine	ALL	0.579
85-Maxillofacial surgery	ALL	1.168
86-Neuropsychiatry	ALL	0.459
90-Medical oncology	ALL	0.736
91-Surgical oncology	ALL	2.772
92-Radiation oncology	ALL	0.905
93-Emergency medicine	NO SURG	1.250
93-Emergency medicine	SURG	2.441
94-Interventional radiology	ALL	1.404
98-Gynecologist/oncologist	ALL	1.921
99-Unknown physician specialty	NO SURG	0.685
99-Unknown physician specialty	SURG	1.164
C0-Sleep Medicine	ALL	0.687
C3-Interventional Cardiology	ALL	2.584
C6-Hospitalist	ALL	0.839
C7-Advanced Heart Failure & Transplant Cardiology	ALL	2.622
C8-Medical toxicology	ALL	1.250
C9-Hematopoietic cell transplantation and cellular therapy	ALL	0.778

*Specialty impacted by the phase-in and the 2023 Risk Index value without the phase-in applied.

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Step (4): Calculate MP RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This percentage was then multiplied by each respective specialty's risk index value as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk

index reflecting the weighted MP costs across all specialties furnishing that procedure. The service specific risk index was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

Impacts of expanded data collection: As we discussed previously in this proposed rule, we are proposing important methodological improvements to our process for calculating MP RVUs. These improvements are in response to comments from interested parties suggesting that we continue to improve data collection to ensure that we use as much specialty-specific data as possible to reflect the most accurate trends in malpractice premiums. When we do not have sufficient premium data for a specialty, our practice has been to use the data from the specialty with the lowest premium. We now have specialty-specific data for many more specialties. However, although the newly captured specialty-specific premium data are more accurate, the new data produce premiums and risk index values that are significantly lower for some specialties than the ones we applied in the absence of sufficient specialty-specific data.

We acknowledge that this reduction in premiums and risk index value is expected to negatively impact payment for services furnished by those specialties that are affected by the improved data collection process. Based on our analyses of the new risk index data, we identified an impact threshold to guide how we could integrate the new information into our calculations and minimize the impact on affected specialties. Specifically, we identified a reduction of approximately ⅓ to the risk index calculated for specialties based on the new specialty-specific premium data compared to the information we had previously used. To mitigate the negative impact on affected specialties, promote payment stability, and prevent potential reductions in access to services for beneficiaries, for specialties for which the use of newly available premium data would result in a 30 percent or greater reduction in the risk index for CY 2023 as compared to the current risk index value for CY 2022, we are proposing to phase in the reduction in MP RVUs over the 3 years that precedes the next update, by ⅓ of the change in MP RVUs for those specialties in each year that have a 30 percent or more threshold reduction in risk index value as a result of the update. For a detailed explanation of how the phase-in will be applied per specialty, a file is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This proposed phase-in is similar to the 2-year phase-in required under section 1848(e)(1)(C) of the Act for changes to the GPCIs when it has been more than one year since the last changes. We propose to phase in the reduction in MP RVUs over 3 years rather than 2 years because the MP risk index values are updated every 3 years. The list of specialties that would be subject to the phase-in under this proposed policy, and the corresponding risk index values for each specialty is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Low volume service codes: As we discuss above in this proposed rule, for low volume service codes, we use the list of expected specialties who may perform a service instead of the claims-based specialty mix when calculating MP RVUs. We finalized this approach in the CY 2018 PFS final rule to address concerns from interested parties about the year-to-year variability in PE and MP RVUs for low volume services (which also includes no volume services). (82 FR 53000 through 53006). Low volume codes are codes that have 100 or fewer allowed services for a year. These service-level overrides are used to determine the expected specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2023, we are soliciting public comment on the list of expected specialties. The proposed list of codes and expected specialties is available on our website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource-based MP RVUs are equal to the total current resource-based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We are proposing to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we proposed to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this final rule, Determination of Practice Expense Relative Value Units. The resource-based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2023 PFS rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent.

Estimates of the effects on payment by specialty type is detailed in section VII. of this proposed rule, the Regulatory Impact Analysis.

Additional information on our methodology for updating the MP RVUs is available in the ''Interim Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

I. Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services

Remote Therapeutic Monitoring (RTM) is a family of five codes created by the CPT Editorial Panel in October 2020, valued by the RUC at its January 2021 meeting, and finalized for Medicare payment in the CY 2022 PFS final rule (86 FR 65114 through 65117). The RTM codes include three PE-only codes and two professional work, treatment management codes.

In the CY 2022 PFS final rule, we finalized refinements to payment for the three PE-only RTM codes: CPT code 98975 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*); CPT code 98976 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*); and CPT code 98977 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*). We valued the three PE-only codes by: (1) cross-walking CPT code 98975 to the PE RVU value of CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*); and by (2) cross-walking CPT codes 98976 and 98977 to the PE RVU of comparable CPT code 99454 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*), a code that includes payment for the medical device used to collect and transmit data.

For the two RTM treatment management codes, we finalized the RUC-recommended work RVU of 0.62 for CPT code 98980 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes*) and the RUC-recommended work RVU of 0.61 for its add-on code, CPT code 98981 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*).

We also finalized the RUC-recommended direct PE inputs for the two treatment management codes without refinement. The direct PE for these two codes includes clinical labor. According to the supporting materials in the RUC recommendations that we accepted, CPT code 98980 includes 40 minutes of activities performed by clinical staff while CPT code 98981 includes 20 minutes of activities performed by clinical staff as direct practice expenses (PE). The RUC materials describe the activities of clinical staff who perform the clinical labor involved in each of these codes as including: communicating with the patient throughout the month, resolving technology or data transmission concerns, reviewing data with the billing practitioner, updating and modifying care plans, and addressing lack of patient improvement. These activities performed by clinical staff of the billing practitioner would be considered services provided incident to the services of the billing practitioner. For more information about ''incident to'' services, see § 410.26.

We expressed concern in the CY 2022 PFS final rule (86 FR 65116) about the treatment management codes as described by the CPT and RUC. In particular, we expressed concern about the inclusion of clinical labor in codes that could be billed by qualified nonphysician healthcare professionals because Medicare Part B does not include a benefit for services furnished ''incident to'' the services of some types of qualified nonphysician healthcare professionals including CSWs, CRNAs, PTs, OTs, and SLPs. Commenters on the CY 2022 PFS proposed rule (86 FR 65116) agreed with our assessment and suggested that we consider developing new coding to resolve the issue. In the CY 2022 PFS final rule, we finalized a policy that permitted therapists and other qualified healthcare practitioners to bill the RTM codes. We stated that where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the services described by the codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the billing PT's or OT's supervision.

The commenters also expressed concern about another issue with the RTM coding that also relates to the clinical labor in the direct PE for the two treatment management codes (86 FR 65116). The commenters acknowledged that the clinical labor involved in these codes, that is, the portion of these services performed by clinical staff incident to the services of the billing clinician, requires direct supervision by the billing practitioner. The commenters stated that direct supervision of clinical staff performing these activities was burdensome, and suggested that physicians and nonphysician practitioners who can bill for ''incident to'' services would be unlikely to use the codes if direct supervision were required. The commenters suggested that we designate CPT codes 98980 and 98981 as care management services or alternatively, that we develop HCPCS G codes that would allow the ''incident to'' clinical labor portions of the services to be furnished under general supervision of the billing physician or nonphysician practitioner.

Since the CY 2022 PFS final rule was issued, we have remained in communication with interested parties. Conversations continue to revolve around the two concerns detailed above related to the clinical labor in the direct PE for the two RTM treatment management codes, CPT codes 98980 and 98981. Thus, for CY 2023 we are proposing to create four new HCPCS G codes with one pair of codes aimed at increasing patient access to remote therapeutic monitoring services and the second pair aimed at reducing physician and NPP supervisory burden.

We note that we also considered requests from interested parties to develop a generic device code for RTM. We have decided to wait to develop a generic RTM device code and instead will seek comment to inform any new coding relating to devices. Thus, we are seeking comment about RTM devices that are used to deliver services that meet the ''reasonable and necessary'' standard under section 1862(a)(1)(A) of

the Act. We seek information related to the types of data collected using RTM devices, how the data that are collected solve specific health conditions and what those health conditions are, the costs associated with RTM devices that are available to collect RTM data, how long the typical episode of care by condition type might last, and the potential number of beneficiaries for whom an RTM device might be used by the health condition type.

Proposal to develop two HCPCS G codes that allow certain qualified nonphysician healthcare professionals to furnish RTM services. In our ongoing dialogue with interested parties, we have heard that a primary reason for developing the RTM codes was to increase beneficiary access to remote monitoring services by allowing the services to be furnished by a broad array of qualified nonphysician healthcare professionals. However, concerns with the CPT coding structure related to the inclusion of clinical labor integral to the professional services have complicated the achievement of those goals. In the CY 2022 PFS final rule, we finalized a policy that permitted therapists and other qualified healthcare practitioners to bill the RTM codes, though we expressed some concerns about the ability of therapists to bill for these codes because the Medicare benefit does not include services provided incident to the services of a therapist (86 FR 65116). We stated that where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the services described by the codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the billing PT's or OT's supervision. We said that these practitioners could bill CPT codes 98980 and 98981 even when the practitioner's Medicare benefit category did not include services furnished incident to their professional services as long as the services were furnished directly by the billing practitioner.

For CY 2023, as a means of increasing beneficiary access to RTM services, as well as more clearly defining the services of RTM for qualified nonphysician healthcare practitioners whose Medicare benefit category does not include services provided incident to their own services, we are proposing two codes that would expressly facilitate RTM services furnished by qualified nonphysician healthcare professionals who cannot bill under Medicare Part B for services furnished incident to their professional services. These codes would not include ''incident to'' activities in the PE. Neither of the two proposed new codes include clinical labor inputs in the direct PE. We are proposing to make the current CPT codes 98980 and 98981 codes non-payable by Medicare.

The two proposed HCPCS G codes are:

- GRTM3 (*Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month*).
- GRTM4 (*Remote therapeutic monitoring treatment assessment services, additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month (List separately in addition to code for primary procedure)*).

For CY 2023, we are proposing a work RVU of 0.62 for the base code, HCPCS code GRTM3, which is the RUC-recommended work RVU we established for CPT code 98980 in the CY 2022 PFS final rule. Similarly, for the add-on code, HCPCS code GRTM4, we are proposing a work RVU of 0.61, which is the RUC-recommended value we established for CPT code 98981. We are proposing to remove the clinical labor inputs in the direct PE for both codes, which will facilitate the use of these codes by qualified nonphysician healthcare practitioners who cannot bill under Medicare Part B for services furnished incident to their professional services. See Table 28: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services for more detailed information about the codes.

Additionally, we note that all the RTM codes including proposed HCPCS codes GRTM3 and GRTM4 would be designated as ''sometimes therapy'' codes, which means that the services could be billed outside a therapy plan of care by physicians and certain NPPs. When the services described by proposed HCPCS codes GRTM3 and GRTM4 are furnished by PTs, OTs, or SLPs, the services would always need to be furnished under a therapy plan of care. We remind readers that RTM services that relate to devices specific to therapy services should always be furnished under a therapy plan of care *regardless of who provides them.* See the Medicare Benefit Policy Manual Chapter 15, Section 230 for more information about the practice of PT, OT, and SLP.

Proposal to develop two HCPCS G codes allowing general supervision of auxiliary personnel. As we described previously in this proposed rule, since the CY 2022 PFS final rule was published, we have continued to hear concerns from interested parties that, as for most ''incident to'' services, the clinical labor activities described in the direct PE of CPT codes 98980 and 98981 must be furnished under the direct supervision of the billing practitioner, which imposes burden on physicians and NPPs who are delivering services to other patients. Thus, for CY 2023, we are proposing to create two HCPCS G codes, one base code and one add-on code, that include clinical labor activities (that is, incident to services such as communicating with the patient, resolving technology concerns, reviewing data, updating and modifying care plans, and addressing lack of patient improvement) that can be furnished by auxiliary personnel under general supervision. These two new G codes, GRTM1 and GRTM2, will include physician work and direct PE inputs as currently described in CPT codes 98980 and 98981 but will allow general supervision of the clinical labor found in the direct PE inputs. See Table 28: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services for more detailed information about the codes and use of the codes.

The two proposed HCPCS G codes are described as follows:

- HCPCS code GRTM1 (*Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes of evaluation and management services*).
- HCPCS code GRTM2 (*Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver over a calendar month; each additional 20 minutes of evaluation and management services during the calendar month (List separately in additional to code for primary procedure*).

For CY 2023, we are proposing a work RVU of 0.62 for HCPCS code GRTM1, which reflects the work RVU for CPT code 98980 that we finalized in the CY 2022 PFS final rule. For HCPCS code GRTM2, we are proposing a work RVU of 0.61, which is the RUC-recommended

value we finalized for the similar CPT code 98981. We are proposing the direct PE inputs associated with CPT codes 98980 and 98981 without refinement for HCPCS codes GRTM1 and GRTM2, respectively. As stated previously, we are proposing to make the current CPT codes 98980 and 98981 codes non-payable by Medicare.

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TABLE 28: Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services

HCPCS Code	Code Descriptor	Global Period	Work RVU Recommendation
GRTM1	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes (Report GRTM1 once each 30 days, regardless of the number of parameters remotely monitored) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2) (At least 16 days of data must be reported) (Do not report GRTM1 for services less than 20 minutes) (Do not report GRTM1 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM3, GRTM4) (Do not report GRTM1 in the same calendar month as 99473, 99474)	XXX	0.62
GRTM2	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure) (Use GRTM2 in conjunction with GRTM1) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2) (Do not report GRTM2 for services less than of 20 minutes) (Do not report GRTM2 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM3, GRTM4)	ZZZ	0.61

HCPCS Code	Code Descriptor	Global Period	Work RVU Recommendation
GRTM3	Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (Report GRTM3 once each 30 days, regardless of the number of parameters remotely monitored) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM3 and GRTM4) (At least 16 days of data must be reported) (Do not report GRTM3 for services less than 20 minutes) (Do not report GRTM3 in conjunction with 93264, 99457, 99458. 98980, 98981, GRTM1, GRTM2) (Do not report GRTM3 in the same month as 99473, 99474)	XXX	0.62
GRTM4	Remote therapeutic monitoring treatment assessment services, each additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (List separately in addition to code for primary procedure) (Use GRTM4 in conjunction with GRTM3) (CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM3 and GRTM4) (Do not report GRTM4 for services less than 20 minutes) (Do not report GRTM4 in conjunction with 93264, 99457, 99458, 98980, 98981, GRTM1, GRTM2)	ZZZ	0.61

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Review of New RTM Device Code: Cognitive Behavioral Therapy Monitoring (CPT Code 989X6)

During its October 2021 meeting, the CPT Editorial Panel replaced two Category III codes: 0702T (*Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days*) and 0703T (*Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional per calendar month*) (*e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response*) with the Category 1 CPT code 989X6, Cognitive Behavioral Therapy Monitoring (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response); initial set-up and patient education on use of equipment; device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*). The CPT Editorial Panel created 989X6 for CY 2023 and deleted Codes 0702T and 0703T.

Also, during the October 2021 meeting, the CPT Editorial Panel revised the code descriptors for the PE-only RTM codes (that is, CPT codes 98975, 98976, and 98977) that CMS finalized in the CY 2022 PFS final rule (86 FR 65114 through 65117) to include ''cognitive behavioral therapy'' as another example of the type of service described by the coding. The RUC indicated that it considered this revision to be editorial.

During the January 2022 RUC review, the definition of new CPT code 989X6 was further refined to read *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily)*

recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days). During the RUC review of CPT code 989X6, specialty societies indicated that the technologies for this service are still evolving. As a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. In response, the RUC recommended that CPT code 989X6 be contractor priced.

Given the anticipatory nature of this code, we agree with the RUC recommendation that this new code should be contractor priced until we learn more about the devices being used to furnish the service. Thus, we are proposing to accept the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. There is no professional work associated with the code. We will work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the new cognitive behavioral monitoring code, CPT code 989X6.

We thank last year's commenters and the many others who have contacted us with their questions and ideas. We appreciate the continuing dialogue about the remote monitoring codes and welcome comments including any additional information that the medical community and other members of the public believe may provide further clarity on how remote patient monitoring services are used in clinical practice, and how they would be most appropriately coded, billed and valued under the Medicare PFS.

J. Payment for Skin Substitutes

1. Background

In the CY 2022 PFS final rule, we finalized an approach for payment of synthetic skin substitutes in the physician office setting. We also announced that we had established a unique HCPCS code for each of ten products for which we had received a HCPCS Level II coding application, and we finalized that those products would be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them. The ten products are as follows: NovoSorb® SynPath™, Restrata® Wound Matrix, Symphony™, InnovaMatrix™ AC, Mirragen® Advanced Wound Matrix, bio-ConneKt® Wound Matrix, TheraGenesis®, XCelliStem®, Microlyte® Matrix, and Apis® (86 FR 65121). After, the CY 2022 PFS Final rule was released, we deleted the ''A'' code that was established for bio-ConneKt Wound Matrix after subsequent determination that a HCPCS Level II code was already established for this product. We note that since we issued the CY 2022 PFS final rule, we have received additional HCPCS Level II coding applications for similarly situated 510(k) cleared wound care management products. Those products have been issued unique HCPCS ''A'' codes and are also payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them.

We also received several comments in response to our finalized policies expressing concern about potential inconsistencies in our policies for synthetic and non-synthetic skin substitutes. We indicated we would take these concerns into future consideration.

2. Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

We believe outlining our HCPCS Level II coding and payment policy objectives in this proposed rule will be beneficial for interested parties, as we work to create a consistent approach for treatment of the suite of products we have referred to as skin substitutes. We have a number of objectives related to refining our Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that all skin substitute products are assigned an appropriate HCPCS code; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the physician office setting; however, interested parties have also indicated that further alignment of our policies across the physician office and hospital outpatient department settings would reduce confusion.

Interested parties have suggested that all skin substitutes, regardless of the inclusion of human, animal or synthetic material in the product should be treated as drugs and biological products. Furthermore, they believe all skin substitute products should receive product-specific ''Q'' codes and receive separate payment under the ASP+6 methodology. They have expressed confusion regarding our assignment of HCPCS Level II ''A'' codes to the 10 skin substitute products in accordance the policy finalized in the CY 2022 PFS final rule, which we typically assign to identify ambulance services and medical supplies, instead of ''Q'' codes, which we typically assign to identify drugs, biologicals, and medical equipment or services not identified by national HCPCS Level II codes. They have indicated that the use of ''A'' HCPCS codes has caused confusion, not only for interested parties, but also for the A/B MACs, who the interested parties assert, have inconsistently processed submitted claims, in part because they are assigned HCPCS ''A'' codes that are treated as supplies which are subject to contractor pricing under the PFS. Additionally, interested parties have expressed concern that physicians and practitioners are hesitant to use the products associated with ''A'' codes because they are unsure if they will be paid appropriately for using those products. When considering potential changes to policies involving skin substitutes, we believe it would be appropriate to take a phased approach over the next 1 to 5 years, that allows CMS sufficient time to consider input from interested parties on coding and policy changes primarily through our rulemaking process, and to account for FDA's regulation of these products, with the goal of avoiding unintended impacts on access to medically necessary care involving the use of these products.

We welcome comment on our policy objectives for creating a consistent approach for treatment of the suite of products we have referred to as skin substitutes. Additionally, we welcome feedback on our phased approach and associated timeline. To achieve our objective of creating a consistent approach for paying for skin substitutes across the physician office and hospital outpatient department setting, we are including similar proposed changes in the CY 2023 OPPS proposed rule, which will be issued near the time this proposed rule is issued.

3. Changing the Terminology of Skin Substitutes

As we work to clarify our policies for these products, we believe that the existing terminology of ''skin substitutes'' is problematic as it is an overly broad misnomer. In the CY 2021 OPPS/ASC final rule with comment period, we revised our description of skin substitutes to refer to a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers (85 FR 80605). We noted that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue. We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that within the hospital outpatient department, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. (85 FR 86066).

While this definition has been updated to provide clarity that synthetic products are considered to be skin substitutes, there is still confusion with the usage of the term skin substitutes because as noted above in the definition, these skin substitute products are technically not a substitute for skin, but rather, a wound covering that is used to promote healing. We have used the current term ''skin substitutes'' to describe the suite of products that are currently referred to as skin substitutes. Additionally, the term ''skin substitutes'' is used within the Current Procedural Terminology (CPT®) code series 15271–8 as maintained by American Medical Association. Also, skin substitute products are generally regulated by the FDA as medical devices under section 510(k) of the Federal Food, Drug and Cosmetic (FD&C) Act and implementing regulations per 21 CFR part 807, or as HCT/Ps solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271.

We believe that improving how we reference these products by using a more accurate and meaningful term will help address confusion among interested parties about how we describe these products, and further, how we pay for them. We are proposing to replace the term ''skin substitutes'' with the term ''wound care management'' or ''wound care management products.'' We believe this new term more accurately describes the suite of products that are currently referred to as skin substitutes while providing enough specificity to not include bandages or standard dressings, which as noted above, are not considered skin substitutes. We understand that our proposed terms contain the words ''care management'' which could be construed to implicate the care management series of AMA CPT codes (for example, 99424–99427, 99437, 99439, 99487, 99489, 99490–99491) that are commonly used by healthcare professionals. We also understand that the use of the word ''management'' in our proposed terms might be construed by some to implicate AMA CPT Evaluation or Assessment and Management (E/M) codes. We would like to clarify that the proposed terms ''wound care management'' and ''wound care management products'' would not implicate the care management series of AMA CPT codes (for example, 99424–99427, 99437, 99439, 99487, 99489, 99490–99491), or our own G-codes that describe care management services. Nor would our proposed terms relate to the AMA CPT E/M codes. Unlike ''care management'' or ''evaluation and management'' codes and services, the proposed terms would describe a category of items or products, not a type of services. Lastly, we also considered alternate terms such as wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds but believe the proposed terms are more technically accurate and descriptive for how these products are used than the alternative's considered.

We solicit feedback on our proposal to change the terminology we use for the suite of products referred to as ''skin substitutes'' to instead use the term ''wound care management'' or ''wound care management products,'' and on the alternative terms we considered including wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds. We are particularly interested in how these products are referenced in current CPT coding and would appreciate feedback from the CPT Editorial Panel and other interested parties on how to address the challenges we discuss above. We also are interested in feedback on other possible terms that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes.

4. Revising Payment for Skin Substitutes

In 2003, the Medicare Modernization Act established the Average Sales Price (ASP) approach for drugs and biologicals as described under section 1847A of the Act. We generally considered skin substitute products to be biologicals in our initial implementation of the ASP methodology. However, with the introduction of synthetic skin substitutes products over the last several years, we are reviewing our categorization of these products, especially as we work to establish payment policies for these products across the various care settings. As explained above, we announced in the CY 2022 PFS final rule the establishment of product specific HCPCS Level II codes for certain products for which we had received a HCPCS Level II coding application. We also finalized that these products would be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them (86 FR 65120). After we issued the CY 2022 PFS final rule, we assigned nine HCPCS ''A'' codes for the synthetic skin substitute products that were addressed in the rule.

In the CY 2022 PFS final rule, we stated that we recognized there was no payment mechanism for synthetic skin substitute products within the PFS, and we acknowledged the need to reconcile the gap in payment for synthetic products in the physician office setting without delay (86 FR 65121). Additionally, as we described in the CY 2022 PFS final rule, a commenter stated that skin substitutes are a heterogenous group and there is an increasing intersection between biological, bioengineered, and synthetic components. This highlights that the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements. The increasing overlap of both synthetic and non-synthetic skin substitute products emphasizes the importance of treating all skin substitute products in a similar manner in terms of coding and payment

After further review, we agree with interested party recommendations that the suite of products referred to as skin substitutes should be treated in a uniform manner across different outpatient care settings. In terms of payment for these products within the office setting, we acknowledge the current variation between contractor

pricing for synthetic skin substitute products and payment based on ASP+6% for non-synthetic skin substitute products; and also the challenges to the clear categorization of products as synthetic or non-synthetic. As a result, we believe establishing a consistent framework for how these products are treated within the physician office and hospital outpatient settings will help ensure equitable access and appropriate payment for these services. As referenced in section II.J.3. of this proposed rule, we believe the term skin substitutes is not all-inclusive or particularly technically accurate, and therefore, we propose to replace the term skin substitutes with 'wound care management products.' Additionally, the term 'wound care management products' accurately reflects our belief that these products are more appropriately considered as supplies incident to a physician service.

In order to ensure we treat skin substitutes consistently in terms of coverage, coding, and payment, we are proposing that skin substitute products that are commonly furnished in the physician office setting be considered as incident to supplies in accordance with section 1861(s)(2)(A) of the Act, effective January 1, 2024. ''Incident to supplies'' refers to supplies that are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness (§ 410.26). Under our proposal, in the office setting, we would no longer pay separately for skin substitute products under the ASP+6% payment methodology.

By categorizing skin substitute products that are furnished in the office setting as incident to supplies, we would consider the cost of the supply used in furnishing a physicians' service through the physician fee schedule practice expense (PE) methodology. Treating these products as incident to supplies would mean that the resource costs for these products would be included in establishing PE relative value units (RVUs) for the associated physicians' service with which they would be furnished. For example, for CPT Code 15271 (application of skin substitute graft, leg or ankle), we establish the PE RVU by considering three separate categories of PE resource costs involved in furnishing the service: clinical labor, supplies, and equipment. Together, these costs are the total direct PE resource inputs. When considering these skin substitute products as a supply, we would add their associated cost to the direct PE inputs for the service with which the product is furnished. For a more detailed description of the PE RVU methodology, please refer to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units in the rule.

We acknowledge that this proposed change to consider skin substitute products furnished in the office setting as incident to supplies would not be implemented immediately in CY 2023. Rather, we would need to transition toward consistent coding and payment for these products. Please refer to section III.O. of this proposed rule for our proposed changes to our process for assigning HCPCS Level II codes to wound care management products. In that section, we are proposing a deadline of 12 months after the effective date of the CY 2023 PFS final rule for applicants to submit HCPCS Level II applications for HCT/Ps . In order to move forward with the proposed changes toward uniform coding, we anticipate that the Q codes for all skin substitute products will be discontinued at the end of CY 2023. We further propose to establish ''A'' codes for all skin substitute products meeting the criteria for a HCPCS Level II code, and propose to contractor price these codes effective January 1, 2024. For CY 2023, skin substitute products that were previously assigned Q codes will continue to be paid under the current ASP+6 payment methodology.

We believe it is necessary to establish an effective date of January 1, 2024, for the proposed payment of skin substitutes in the non-facility setting as incident to supplies in order to align with the HCPCS Level II coding proposals for wound care management products as described in section III.O., to ensure all interested parties have the same opportunity to effectively transition toward the coding and payment changes. Additionally, we intend to engage with interested parties via an open-door forum/listening session to receive feedback on this proposal.

To summarize, we propose to treat skin substitutes (including synthetic skin substitutes) as incident to supplies as described under section 1861(s)(2)(A) of the Act when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024. This proposal would mean skin substitutes are treated in the same manner for purposes of payment when furnished in non-facility settings, and would be consistently contractor priced through CY 2024. Given these significant changes, we believe maintaining the current treatment of these products for purposes of payment during CY 2023 will aid interested parties through the transition. We also propose to discontinue the use of the term skin substitutes beginning January 1, 2024 and to instead refer to this suite of products as ''wound care management products.'' We solicit feedback on our proposals.

K. Proposal To Allow Audiologists To Furnish Certain Diagnostic Tests Without a Physician Order

Audiologists are recognized under Medicare Part B to provide certain diagnostic audiology services as defined at section 1861(ll)(3) of the Act. Specifically, the statute describes audiology services that include such hearing and balance assessment services as the audiologist is legally authorized to perform under State law, as would otherwise be covered if the services were furnished by a physician. The definition of qualified audiologist appears at section 1861(ll)(4)(B) of the Act. Currently, the only other provision in the Medicare statute that relates to audiology services is found at section 1862(a)(7) of the Act, which excludes payment for hearing aids and related examinations. This exclusion is codified at § 411.15(d)(1) which precludes payment for hearing aids or examinations for the purpose of prescription, fitting, and changing hearing aids. There are no other Medicare statutory provisions addressing audiologists or audiology services. Diagnostic tests are included as a Medicare Part B benefit under section 1861(s)(3) of the Act.

For many diagnostic testing services, payment under the PFS can be made in two separate components of the service when parts of the services are furnished by two different physicians, practitioners, or other suppliers: the technical component (TC) and the professional component (PC). The TC is the portion of the service that involves the collection of information from the patient—for example, a radiological image, sample, specimen, or interrogatory study. When the TC is furnished separately, the ''TC'' modifier is used with the relevant HCPCS code to bill for the service under the PFS. The PC of a diagnostic test is the portion of the service involving the interpretation of the collected information by a physician or other practitioner. When the PC is furnished separately, the service is coded with modifier ''26''. When the same physician or practitioner furnishes both the TC and PC of the service, the relevant HCPCS code (known as the ''global'') is billed

without a modifier. We have established general requirements for furnishing and billing diagnostic tests at § 410.32.

In the CY 1997 PFS final rule, we established in regulations at § 410.32(a), based on long-standing manual provisions, that all diagnostic tests, including audiology tests, must be ordered by the physician who is treating the beneficiary who will use the results to manage the beneficiary's care. We believed this requirement was necessary to ensure that the physician had a relationship with the beneficiary, and would ensure the tests were reasonable and medically necessary, as well as prevent patterns of abuse. At the same time, we finalized a regulatory provision at § 410.32(c) (later redesignated to § 410.32(a)(2)) to recognize as the treating practitioner for the purpose of ordering diagnostic tests certain nonphysician practitioners (NPPs) who are authorized under the statute to provide services that would be physician services if furnished by a physician when they are operating within the scope of their State license. The NPPs who can serve as the treating practitioner for purposes of ordering diagnostic tests include physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) (defined in sections 1861(s)(2)(K)(i) and (ii) of the Act, respectively), certified nurse-midwives (defined in section 1861(gg) of the Act), qualified psychologists (defined in section 1861(ii) of the Act), and social workers (defined in section 1861(hh) of the Act)) (61 FR 59497 through 59498). We note that all of these NPPs are included as practitioners who must accept Medicare payment on an assignment-related-basis under section 1842(b)(18)(C) of the Act. As such, these NPPs can only collect any applicable cost-sharing from the patient, and cannot balance bill the patient for additional amounts above the Medicare payment amount. The regulation reflecting the ordering requirements for diagnostic tests has not been substantively amended since that time, except to add an exception to the treating practitioner ordering requirement for screening mammography and, in response to the PHE for COVID–19 to add a limited exception for a single, otherwise-covered COVID–19 diagnostic test (and one otherwise covered diagnostic laboratory test for flu or similar respiratory condition needed to diagnose COVID–19) per patient per year during the PHE.

In the CY 1998 final rule (62 FR 59057 through 59070), we also amended § 410.32(a) to clarify that the ordering requirement is based on the exclusion in section 1862(a)(1)(A) of the Act and contained in § 411.15(k)(1); that is, diagnostic testing services that do not meet the ordering requirements in § 410.32(a) are considered not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. We explained that we found tests not demonstrably reasonable and medically necessary if they are not ordered by the beneficiary's treating physician or practitioner who will use the test results to manage the beneficiary's condition or symptom. Also in the CY 1998 PFS final rule, while we continued to require physician supervision for most diagnostic tests, we amended our regulation to except diagnostic tests personally furnished by audiologists (as well as psychologists and certain physical therapists board-certified in electrophysiology) from the physician supervision requirement.

As explained above, all of the NPPs that we recognize as treating practitioners in § 410.32(a)(2) for purposes of the diagnostic test order requirement who must accept Medicare payment on an assignment-related basis can only collect any applicable cost-sharing from the patient and cannot balance bill the patient for additional amounts. Audiologists are not NPPs as defined by the statute (that is, they are not listed at section 1842(b)(18)(C) of the Act). However, beginning in 2008, we allowed audiologists to enroll in the Medicare program so that they could independently bill for their audiology services rather than relying on physicians or other enrolled practitioners to bill on their behalf. As such, audiologists are not required to accept payment on an assignment-related basis.

Over the past several years, interested parties have requested that CMS eliminate the treating physician or other practitioner order requirement for the hearing and balance assessment services furnished by audiologists. They have suggested that CMS has the administrative authority to eliminate the order requirement for audiology services via notice and comment rulemaking, and that doing so would enable greater access to these important services. The interested parties believe that an order from the treating physician or practitioner is not required by the statute, and that audiology services are covered unless they are otherwise excluded, such as because they are not reasonable and necessary in a particular circumstance. To support their points, these interested parties shared with us a report prepared in 2020 by a consultant concluding that removal of the treating physician or practitioner ordering requirement for audiology hearing and balance assessment services would result in an estimated savings to Medicare over a 10-year period of approximately $108 million, which includes a savings of $36 million in beneficiary copayments. These savings estimates are based on projected Medicare payments and beneficiary copayments that would not occur if Medicare beneficiaries directly accessed the audiology hearing and balance services furnished by an audiologist without the order of a treating physician or other practitioner. In addition, we have heard from interested parties that an order is not required for audiology services by certain other public or private health insurers including Medicare Advantage plans, Medicaid, plans under the Federal Health Benefit Program, and the Veterans Administration. We do not know the scope of services that are covered by these plans or insurers when furnished by audiologists, including whether these health insurers cover only hearing and balance assessment services (as the Medicare program does in accordance with the statute) or also hearing aid examinations for the prescription, fitting, and programming of hearing aids or other services excluded from payment under Medicare Part B and/or whether only some or all of the plans allow payment directly to audiologists for some or all of the covered services without a physician/NPP order. Additionally, we note that some of these health insurance programs involve closed systems with greater levels of interprofessional communication and control (for example, within certain accountable care organizations (ACOs), managed care plan networks, or through various Veterans Affairs medical centers). In contrast, the physicians and practitioners furnishing care under the fee-for-service Medicare Part B program often practice independently from each other, which can pose barriers to communication and coordination of care between health care professionals such as audiologists and the treating physicians or other practitioners.

In addition, the nature of audiology services personally furnished by audiologists is such that these services are often billed based on the audiologist's reassignment of billing rights by an entity other than the furnishing audiologist, so we are currently unable to determine the number of audiologists furnishing these services or the full scope of beneficiary

utilization of these services in those settings.

While we believe that CMS has the administrative authority to remove the treating physician or practitioner order requirement for audiology hearing and balance assessment services via notice and comment rulemaking, we do not agree with the suggestions of interested parties that audiologists should be considered in the same way as the NPPs we recognized as treating practitioners for purposes of the order requirement under § 410.32(a)(2). Specifically, we allowed the NPPs (including PAs, NPs, and CNSs) to order diagnostic tests for the beneficiaries they treat, and we continued to require that the results of the tests be used in the management of the patient's specific medical problem. In these cases, the relationship of the patient to the NPP who orders diagnostic tests and uses the results in managing the beneficiary's medical condition serves to provide assurance that the services are medically necessary. In contrast, audiologists are not recognized under Medicare Part B to treat or manage patients. We consider audiologists' services to be more specialized that those of other physicians and NPPs who provide diagnostic services. That is, their diagnostic tests are more limited and focused in scope than others furnishing services under the Medicare Part B benefit for diagnostic tests at section 1861(s)(3) of the Act. Unlike PAs, NPs or CNSs who may bill for E/M services, and for whom Medicare Part B covers services and supplies incident to their own professional services as provided in the regulation at § 410.26, the scope of audiology services under the Medicare Part B statute includes only diagnostic hearing and balance assessment services. We are concerned that removal of the order requirement for hearing and balance services furnished by audiologists could lead to the furnishing and payment of services that are not used by a treating physician or practitioner in the management of the patient's medical condition, and thus, not medically necessary. We are also concerned about patient safety if Medicare beneficiaries seek hearing and balance services directly from audiologists without the involvement of a treating physician or practitioner. For example, the beneficiary could have an acute condition or symptom such as acute sensorineural hearing loss resulting from a viral neuronitis that needs to be diagnosed and treated by a physician or practitioner on an emergent basis, and that care could be delayed if the beneficiary first sought care directly from an audiologist. As an additional example, disequilibrium has many possible causes, including potentially life threatening cardiologic (for example, arrythmias, heart attack or cardiac ischemia) and neurologic etiologies (for example, migraines, TIAs (transient ischemic attacks), strokes). The wide variety of possible causes of disequilibrium with some of these in both categories being potentially life threatening (for example, stroke, heart attack, arrythmias) speaks to the importance of a physician or NPP being involved in the initial patient assessment. Such an assessment would include a careful history, a physical examination, and immediate office-based testing (for example, EKG) to look for some of the more critical possible causes of disequilibrium, and the physician or NPP would determine the plan for the progression of the outpatient workup. That is to say, the physician or NPP would decide, given the history and clinical exam, whether the evaluation should continue along cardiologic, neurologic, or vestibular perspectives—the latter of which could possibly result in an order/referral to an audiologist for balance assessments using the vestibular dysfunction testing codes. For these reasons, we believe patients with disequilibrium would be best served by seeing a physician or NPP before being referred to an audiologist as appropriate. Furthermore, as previously noted, audiologists are not required to accept Medicare payment on an assignment-related basis, and therefore, can balance bill the beneficiary. We are concerned that the removal of the treating physician or practitioner ordering requirement, and potentially increased volume of audiology services, could lead to unnecessary costs to beneficiaries. In addition, in the absence of a required order of the treating physician or practitioner, we are concerned that the direct access to audiologists might incentivize changes in behavior and practice patterns among audiologists that could lead to overutilization of audiology services.

We have carefully considered the interested parties' requests to remove the treating physician or practitioner order requirement for diagnostic audiology hearing and balance assessment services. We believe it would be appropriate to provide a limited exception to the order requirement for diagnostic hearing testing services furnished by audiologists in order to broaden patient access to these services. In response to the requests of interested parties, we are proposing to amend our regulation by adding a paragraph at § 410.32(a)(4) to remove the order requirement under certain circumstances for certain audiology services furnished personally by an audiologist for non-acute hearing conditions. These non-acute hearing conditions would not include balance assessments that are used for patients with disequilibrium, because as we explained above, the physician/NPP needs to first evaluate the patient clinically due to the many serious medical conditions the beneficiary might have, and ensure the patient is cleared medically before setting them on track to receive vestibular function tests, possibly from an audiologist. The list of audiology services for which Medicare payment can be made when an audiologist personally performs them on the order of the treating physician or NPP can be found on the Medicare physician fee schedule web page under the link titled ''Audiology Services'' at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched.* We propose to permit the services described by the codes listed in Table 29 to be furnished under the proposed exception without the order of the treating physician or NPP. We note that Table 29 does not include the codes for vestibular function tests in the code ranges of 92517–92519 and 92537–92549 because, as discussed above, we believe it is in the clinical interest of the beneficiary to be assessed by a treating physician or NPP for potentially serious medical implications of disequilibrium symptoms, including cardiologic and neurologic etiologies before they can be cleared and referred for vestibular function tests.

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TABLE 29: Proposed Codes for Tests that can be Encompassed by HCPCS Code GAUDX that Audiologists can Provide without a Physician or NPP Order/Referral

CPT Code	Short Descriptor
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92562	Loudness balance test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92571	Filtered speech hearing test
92572	Staggered spondaic word test
92575	Sensorineural acuity test
92576	Synthetic sentence test
92577	Stenger test speech
92579	Visual audiometry (vra)
92582	Conditioning play audiometry
92583	Select picture audiometry
92584	Electrocochleography
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92602	Reprogram cochlear implt <7
92603	Cochlear implt f/up exam 7/>
92604	Reprogram cochlear implt 7/>
92620	Auditory function 60 min
92621	Auditory function + 15 min
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92640	Aud brainstem implt programg
92561	Aep hearing status deter i&r
92562	Aep thrshld est mlt freq i&r
92563	Aep neurodiagnostic i&r

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We are proposing to create HCPCS code GAUDX (*Audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids; (service may be performed once every 12 months)* to describe these audiology services furnished personally by an audiologist without the order of the treating physician or other practitioner. We believe that limiting the audiology services that can be furnished without an order to include only hearing conditions that are non-acute in onset and balance services (patients with disequilibrium symptoms) by removing the CPT codes for vestibular dysfunction would be appropriate to address our patient safety concerns. We also propose to specify in the code descriptor for HCPCS code GAUDX that the audiology services can be performed only once every 12 months. We believe this limitation is appropriate to avoid potential program integrity issues, such as audiologists billing for GAUDX with a greater frequency, or providing services that are not reasonable and necessary for the treatment of the patient's illness or injury. We selected once every 12 months, rather than every 6 months, for two reasons. The first is because 6 months did not seem long enough for a new, non-acute hearing condition to arise, and if an acute hearing condition were to onset, it would necessitate an evaluation with a physician/NPP. The second reason is that, at any time, the beneficiary may always elect to see their physician/NPP for any hearing conditions—acute or non-acute—or for conditions with disequilibrium symptoms.

Under this proposal, an audiologist would be able to bill code GAUDX once every 12 months for a beneficiary. The GAUDX code would include and be used to bill for any number of audiology services furnished in that particular

encounter with the beneficiary. Since the proposed GAUDX code is generic, the tests provided could include those that are split into PC/TC and those that are not. As with all services, the actual tests provided and their results would need to be documented in the medical record, for purposes of medical review. Further, we propose that no more than one unit of code GAUDX could be billed—that means ''1'' is inserted in the ''days or units'' block 24G on the CMS 1500 professional claim form. We are also concerned that beneficiaries may receive services billed as code GAUDX from more than one audiologist in the 12-month period and/or be mistaken or misled into thinking that code GAUDX represents a screening/preventive service which Medicare does not cover. To avoid the potential for inappropriate use of HCPCS code GAUDX, we plan to establish system edits through our usual change management process to ensure that GAUDX is only paid once every 12 months, per each beneficiary. We note that the code descriptor proposed for GAUDX could be billed for patients seeking care for non-acute hearing conditions, and that the furnished audiology services would still have to be medically necessary. Under our proposal, after receiving audiology services from an audiologist accessed directly without the order of a treating physician or practitioner, the beneficiary would have to wait a full 12 months before receiving additional diagnostic tests from an audiologist without a physician/NPP order. The beneficiary would remain free to seek care from a treating physician (or/NPP) if needed, and that care could potentially include a referral with an order for further diagnostic testing furnished by an audiologist.

To value HCPCS code GAUDX, we propose to use the combined values of CPT codes 92557 (*Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)*) and 92567 (*Tympanometry (impedance testing)*), which we believe would represent a typical service provided by audiologists. We chose CPT Codes 92557 and 92567 as typical because they make up 72 percent of all billings for audiologists; and, when all physician and practitioner specialties are considered, including audiologists, code 92557 is billed with code 92567 over 60 percent of the time and code 92567 is billed with code 92557 over 83 percent of the time in the same clinical encounter, according to Medicare claims data.

Thus, we propose a total work RVU of 0.8 for GAUDX, calculated by combining the 0.60 work RVU for CPT code 92557 and 0.20 work RVU for CPT code 92567. We are proposing to establish the PE value for GAUDX by combining the unduplicated PE of CPT codes 92557 and 92567. Specifically, we propose to include the following direct practice expense (PE) inputs for supply items: two SD046 (Ear tip, tympanometry probe), two SJ053 (Swab pad, alcohol), one SM0251 (Specula tips, otoscope), one (SK059) sheet of recording paper, and two SD047 (Ear tip insert with sound tube); and the following direct PE inputs for equipment: EQ054 (Audiometric soundproof booth (exam and control room)) for 20 minutes, EQ053 (Audiometer, clinical, diagnostic) for 20 minutes, and EQ244 (Tympanometer with printer) for 4 minutes. We also propose to apply the same provisions for code GAUDX as those set for 92557 and 92567 (for example, PC/TC indicator, bilateral indicator, physician supervision indicator, etc.), as they now appear in the PFS Relative Value file found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.*

We believe that proposed HCPCS code GAUDX, if finalized, will allow us to better understand the scope of beneficiary access to these services with or without the order requirement. We also believe that proposed HCPCS code GAUDX, if finalized, will allow us to better assess possible burdens to the beneficiary when attempting to access these services. Given the makeup and intended use of proposed code GAUDX, we would like to increase our understanding about how and where these audiology services would be provided without the order of a treating physician or practitioner. We are also requesting comments from interested parties about what settings might represent the typical places of service and which institutional providers might bill for HCPCS code GAUDX.

L. Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

1. Background on Medicare Payment for Dental Services

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made under Medicare Part A for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at 42 CFR 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

However, under our current policy, we make payment under both Medicare Part A and Part B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act or our regulation at § 411.15(i). We make payment when a doctor of dental medicine or dental surgery (hereinafter referred to as a ''dentist'') furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician treating the primary medical illness. In these limited circumstances, Medicare payment can be made for dental services such as, but not limited to, the wiring of teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, and/or an oral or dental examination on an inpatient basis performed as part of a comprehensive workup prior to renal transplant surgery. (See Medicare Benefit Policy Manual (IOM Pub 100–02, Chapter 15, section 150); and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6)). Medicare Administrative Contractors (MACs) make claim-by-claim determinations as to whether a patient's circumstances do or do not fit within the terms of the preclusion and exception specified in section 1862(a)(12) of the Act and § 411.15(i) of our regulations, and in accordance with the CMS manual provisions.

We have received feedback from interested parties suggesting that our interpretation of section 1862(a)(12) of the Act is unnecessarily restrictive, which may contribute to inequitable distribution of dental services for Medicare beneficiaries. Additionally, a recent report from the National

Institutes of Health, ''Oral Health in America Advances and Challenges,'' discusses how unequal distribution of dental services and prohibitive costs, particularly for older adults who are at the highest risk for poor oral health, can lead to and further complicate the treatment of other medical conditions (for more information, see *https://directorsblog.nih.gov/2022/06/14/using-science-to-solve-oral-health-inequities/*). The interested parties also suggest that there are instances where dental services are directly related to the clinical success of an otherwise covered medical service under Medicare Parts A and B, and that the regulation at § 411.15(i) should be amended to reflect that Medicare payment is available in these circumstances. Recognizing that there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we believe that there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. We also believe that there are circumstances where the dental services are in direct connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and are not inextricably linked to the clinical success of a covered medical service. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act except when, due to the patient's underlying medical condition and clinical status, or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

To provide greater clarity to our current policies and respond to issues raised by interested parties, as described in section II.L.2 of this proposed rule, we are: (1) proposing to clarify our interpretation of section 1862(a)(12) of the Act and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposing and seeking comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; (3) requesting comments on other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services; (4) requesting comments on the potential establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services; (5) requesting comment on other potentially impacted policies; and (6) requesting comment on potential future payment models for dental and oral health care services. We welcome public comments on these areas.

2. Proposals To Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services and Request for Comment

a. Proposed Payment for Inpatient Hospital Dental Services and Request for Comment

As explained above, under our interpretation of the statute and our current regulation, and as reflected in our regulation and manuals, items and services furnished in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth generally are not covered, and no payment may be made for them under either Medicare Part A or Part B. Section 1862(a)(12) of the Act and our regulation at § 411.15(i) includes an exception to allow Medicare Part A payment to be made for inpatient hospital services in connection with the provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. We believe that there are instances in which a Medicare beneficiary may require dental services that are in direct connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth such that the application of the Medicare Part A payment exception would apply when hospitalization is required because of: (1) a patient's underlying medical condition and clinical status; or (2) the severity of the dental procedure. Under these circumstances, we would continue to apply the exception under section 1862(a)(12) of the Act, and make payment for inpatient hospital services. We are interested in receiving public comments on what professional services, including, but not limited to dental services, may occur during and prior to the patient's hospitalization or procedure requiring hospitalization under this exception. We may consider finalizing, based on our review of public comments, additional payment policies in this area.

b. Proposal To Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services

As explained above, Medicare payment can be made for inpatient hospital services associated with dental services that fall within the statutory exception under section 1862(a)(12) of the Act. However, under our current policy, if a dental service and other related services (for example, anesthesia or imaging services) are performed as incident to and as an integral part of a covered procedure or service performed by a dentist, the total service performed by the dentist is covered, and payment can be made under Medicare Parts A and B as appropriate. This policy is based on the idea that some dental services that would ordinarily be excluded by statute from payment are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. When that is the case, then we believe those dental services are not in connection with dental services within the meaning of section 1862(a)(12) of the Act, but are instead inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. As such, we propose to interpret the statute under section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services and allow payment to be made, regardless of whether the services are furnished in an inpatient or outpatient setting. Under these circumstances, we propose that the exclusion under section 1862(a)(12) of the Act would not apply, because the service is not in connection with the

care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but instead is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

As described in section II.L.1. of this proposed rule, in a limited number of circumstances, Medicare Part B currently pays for dental services under the PFS when a dentist furnishes a service(s) that is integral to the covered primary procedure or service rendered when treating the primary medical illness. Our current payment policies for dental services are contained in manual provisions (The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100–02, Chapter 15, section 150) and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6)) that reflect the proposed interpretation of section 1862(a)(12) of the Act discussed above.

Our payment policy contained in Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100–03, Chapter 1, Part 4, section 260.6)[74] (herein ''the NCD Manual'') provides for payment of an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery. We believe Medicare payment is permitted under this manual provision for such a dental or oral examination prior to renal transplant surgery, because the examination is inextricably linked to, and substantially related and integral to the clinical success of, the renal transplant procedure. As such, we believe such services are not subject to the payment preclusion under section 1862(a)(12) of the Act. However, we believe that comprehensive workups prior to renal transplant surgery, including related dental examinations, can occur in either the inpatient and outpatient setting. As such, we are proposing to provide Medicare payment for oral or dental examinations performed as part of a comprehensive workup prior to renal transplant surgery when these services occur in either the inpatient or outpatient setting, and revise our regulation at § 411.15(i) accordingly.

The NCD Manual goes on to state that, when performing a dental or oral examination, a dentist is not recognized as a physician under section 1861(r) of the Act. We believe this statement is based on an unnecessarily narrow reading of section 1861(r) of the Act, and is also not consistent with other manual provisions. The statutory definition of physician includes a doctor of dental surgery or of dental medicine in section 1861(r)(2) of the Act, and a similar definition of physician is included in our IOM Pub 100–1, Section 70.2[75] when dental or oral examinations, and specific treatments, are within the State scope of practice for the dentist. As such, we are proposing to amend § 411.15(i) to clarify that Medicare Part B coverage and payment can be made for such a dental or oral examination prior to renal transplant surgery when performed by a doctor of dental surgery or dental medicine as defined in section 1861(r)(2) of the Act.

The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100–02, Chapter 15, section 150) (herein ''the MBP Manual'') states that if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.[76] The MBP Manual continues by providing several specific examples where CMS would pay for dental services:

- The reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor (other than for dental purposes).
- The wiring of teeth when done in connection with the reduction of a jaw fracture.
- The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.
- The dental splint when performed in conjunction with treatment that is determined to be a covered medical condition.

Specifically, in the MBP Manual, we describe that the reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure and therefore would not generally be eligible for payment. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service. In the case of the procedure of ridge reconstruction occurring in conjunction with the surgical removal of a tumor, we believe that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services, that is, the removal of a tumor; and therefore, Medicare Part A and Part B payment could be made. Additionally, the MBP Manual explains that Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture. Once again, we believe that the dental services of wiring of the teeth are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, which in this case is the reduction of a jaw fracture, and therefore, Medicare Part A and Part B payment could be made. Likewise, the MBP Manual states that the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also currently covered. We continue to believe that in this clinical scenario the dental services related to teeth extraction are inextricably linked to, and substantially related and integral to the clinical success of, the radiation treatment of neoplastic disease; and therefore, Medicare Part A and Part B payment could be made. The Manual also describes a specific situation in which certain dental services may be considered a covered service, depending on whether the underlying medical condition is deemed to be covered. The Manual explains that dental splints used to treat a dental condition are generally excluded from coverage under section 1862(a)(12) of the Act, but if the treatment is determined to be a covered medical condition (that is, dislocated upper/lower jaw joints), then the splint can be covered. We believe that dental splint services could be covered and paid, because the dental services could be inextricably linked to, and substantially related and integral to the clinical success of, a covered medical service, such as treatment of a dislocated jaw. Therefore, we are proposing to clarify and modify the regulations text at § 411.15(i) to include this scenario of dental splints used in the treatment of a covered medical condition. We seek comments on this aspect of the proposal.

Therefore, we are proposing to codify and clarify in the regulation at § 411.15(i) that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, including (1) reconstruction of a ridge when it is performed as a result of and

[74] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.*

[75] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS050111.*

[76] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS012673.*

at the same time as the surgical removal of a tumor; (2) the wiring or immobilization of teeth when done in connection with the reduction of a jaw fracture; (3) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (4) a dental splint only when used in conjunction with covered treatment of a medical condition. This proposal would constitute a clarification to existing policy, as we are codifying in regulation existing manual provisions.

The MBP Manual states that payment can be made under Medicare Parts A and B for a covered dental procedure regardless of where the service is performed, noting that the hospitalization or non-hospitalization of a patient has no direct bearing on the coverage, payment, or exclusion of a given dental procedure in specific circumstances. As such, dental services that are not excluded from Medicare payment under section 1862(a)(12) of the Act could be appropriately furnished in inpatient or outpatient settings. We propose to clarify in the regulation at § 411.15(i) that payment for dental services that do not fall within the scope of section 1862(a)(12) of the Act, and that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, could be made regardless of whether the services are furnished on an inpatient or outpatient basis. We seek comments on whether it is clinically appropriate for these services to be furnished in inpatient or outpatient settings.

The MBP Manual further states that the coverage of services such as the administration of anesthesia, diagnostic x-rays, and other related procedures depends upon whether the primary procedure being performed by the dentist is itself covered. The MBP Manual explains that an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered, while a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered. In order to clarify and codify this current policy, we propose to amend our regulation at § 411.15(i) to provide that payment can be made for dental services provided in conjunction with medical services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, such as X-rays, administration of anesthesia, and use of the operating room.

The MBP Manual also specifies that payment can be made for services and supplies furnished incident to other dental services for which Medicare payment can be made, for example, services furnished incident to the dentist's professional services by a dental technician or registered nurse under the dentist's direct supervision. Medicare payment policy for services furnished incident to the services of the billing practitioner are contained in § 410.26 of our regulations.

Additionally, the MBP Manual provides that when an excluded service is the primary procedure involved, dental services are not covered, regardless of complexity or difficulty. The MBP Manual describes an example of the extraction of an impacted tooth as not covered, and goes on to state that certain procedures, including an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy, are excluded from coverage when either of these procedures is performed in connection with an excluded service, for example, the preparation of the mouth for dentures. Additionally, the MBP Manual states that the removal of a *torus palatinus* (a bony protuberance of the hard palate) may be a covered service, but notes that it is often provided in connection with an excluded service (that is, the preparation of the mouth for dentures), and in that event, Medicare does not pay for this procedure.

We are not proposing to modify this policy. No payment is made for dental services when an excluded service is the primary procedure involved. Our interpretation of section 1862(a)(12) of the Act allows for Medicare payment when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. Therefore, no payment is made when dental services are related to medical services that are not covered, even if the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the non-covered services. The proposed amendment to § 411.15(i) would specify that, in order for Medicare payment to be made, the dental services must be inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

Under our proposal to clarify and codify our current payment policy for dental services, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered medical services. When such medically necessary dental services are furnished by a physician or practitioner, including a dentist, Medicare Part A or B payment can be made for the dental services and other services integral or incident to those dental services. Specifically, such services include:

- The wiring of teeth when done in connection with an otherwise covered medical service,
- The reduction of a jaw fracture (such as services described by CPT code sets 21440–21490),
- The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease (such as services described by Current Dental Terminology (CDT) [77] codes D7140 and D7210 for ICD–10 C41.1 Malignant neoplasm of mandible),
- Dental splints only when used in conjunction with covered treatment of a medical condition (such as dislocated upper/lower jaw joints), or
- An oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery (such as services described by ICD–10 Z94.0, and codes D0150, D0180, or D0160).

We propose that Medicare Part A and B payment for these dental services can be made, because the services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services. We further seek comment on whether, given current clinical advances, the descriptions of these dental services are clinically accurate and appropriate. For example, we are interested in whether the phrase ''wiring of the teeth'' is still clinically accurate or if other terminology would be more appropriate.

Given that such dental services would not be subject to the preclusion on payment under section 1862(a)(12) of the Act, Medicare would make payment to the furnishing dentist or another physician or practitioner for the professional dental services. As described in the MBP Manual, payment may also be made for services and supplies furnished incident to those dental services furnished by the dentist or other physician or practitioner, and for other ancillary services integral to the dental services. For example, Medicare payment could be made for services furnished incident to the professional dental services by auxiliary personnel, such as a dental hygienist,

[77] *https://www.ada.org/publications/cdt.*

dental therapist, or registered nurse who is under the direct supervision of the furnishing dentist or other physician or practitioner, if they meet the requirements for ''incident to'' services as described in § 410.26 of our regulations. When such dental services are furnished in a facility setting, such as an inpatient acute care hospital or hospital outpatient department, payment for the facility or ancillary services would be made under the applicable payment system.

In summary, we are proposing to amend § 411.15(i) to codify that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, an otherwise covered medical service. We further propose to amend § 411.15(i) to include examples of services for which payment can be made under Medicare Parts A and B on that basis. Specifically, we propose to include as examples the following dental services for which payment is permitted under our current policy: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition. We further propose that Medicare payment would be made for these dental services regardless of whether the services are furnished in an inpatient or outpatient setting, and we propose that payment can also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, use of an operating room, other facility services.

We seek comment on all aspects of this proposal. If finalized, we note that we will make conforming changes to the MBP Manual to reflect changes or clarifications, and to remove any text that is no longer applicable. We will also make conforming changes to other Manual provisions or National Coverage Decision policies as necessary.

As discussed, MACs may determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). The proposed policies outlined in this section of this proposed rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed within this proposed rule and the proposed amendments to § 411.15(i).

c. Proposed Update to Current Payment Policies for Dental Services

As discussed in section II.L.2 of this proposed rule, we are proposing that payment can be made under Medicare Parts A and B for dental services such as the reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor, the wiring or immobilization of the teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, dental splints only when used in conjunction with covered treatment of a medical condition, and an oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery. We believe, after further review of current medical practice, through consultations with interested parties and our medical officers, that there are additional circumstances that are clinically similar to these examples, and where Medicare payment for the service could be made, because the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical service(s).

For example, after further review, we believe that if a patient requiring an organ transplant has an oral infection, the success of that transplant could be compromised if the infection is not properly diagnosed and treated prior to the transplant surgery. Without an oral or dental examination to identify such an infection, and the necessary treatment, such as restorative dental services, to eradicate it prior to the transplant procedure, the patient's ability to accept the organ transplant could be seriously complicated or compromised. Examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999). If such an infection is not treated prior to transplant, and immunosuppressant therapy is initiated to preserve the transplant, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to sepsis. Similarly, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement [78] or valvuloplasty procedures, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves, seeding surrounding cardiac muscle tissues involved with the surgical site, and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient. Because an oral or dental infection can present substantial risk to the success of these procedures, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present, we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, these other covered medical services. We note that, in these circumstances, the necessary treatment to eradicate an infection may not be the totality of recommended dental services for a given patient. For example, if an infected tooth is identified in a patient requiring an organ transplant, cardiac valve replacement, or valvuloplasty procedure, the necessary treatment would be to eradicate the infection, which could result in the tooth being extracted. Additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source prior to surgery. Therefore, such additional services would not be inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant, cardiac valve replacement, or valvuloplasty services. As such, no Medicare payment would be made for

[78] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834-7819.1991.tb00724.x.*

the additional services that are not immediately necessary prior to surgery to eliminate or eradicate the infection.

As discussed, we believe that there are circumstances where the clinical success of medical or surgical services required for a successful organ transplantation, cardiac valve replacement, and valvuloplasty procedure may require the performance of certain dental services. As such, we propose to amend our regulation at § 411.15(i)(3) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B for such dental services. We are proposing to amend § 411.15(i) to include examples of payable services under Medicare Parts A and B, as: (1) the dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure; and (2) the necessary dental treatments and diagnostics to eliminate the oral or dental infections found during a dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We believe that clinical practice is such that these services can occur within the inpatient hospital or outpatient setting, and we further propose that Medicare Parts A and B would make payment for these dental services, as applicable, regardless of whether the services are furnished in an inpatient or outpatient setting. Furthermore, we propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

We seek comment on this proposed policy and our proposed amendments to § 411.15(i)(3) to specify that payment under Medicare Parts A and B can be made for an oral or dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We propose to continue to contractor price the dental services for which payment is made currently, and for the dental services that can be made under the proposed amendments to § 411.15(i)(3) for CY 2023, or until we have further data to establish prospective payment rates. We also seek public comment on the expected utilization of these services.

We solicit comment on these proposals.

i. Other Clinical Scenarios for Dental Services Integral to Other Covered Medical Services

In addition to the examples of dental services for which payment is made under our current policy, and dental services to avoid risk of an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures, we believe there may be other clinical scenarios where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. These could include certain dental exams and medically necessary diagnostic and treatment services prior to treatments for head and neck cancers, such as radiation therapy with or without chemotherapy, or the initiation of immunosuppressant therapy, such as those used during cancer treatments, where the standard of care is such that it is clinically advisable to eliminate the source of infection prior to proceeding with the necessary medical care, or the standard of care for the primary medical condition would be significantly materially compromised if the dental services are not performed. As with any assessment of patient health prior to initiating immunosuppressant therapy, it may be necessary to eradicate all sites of infection, including oral infections, prior to suppressing the immune system, regardless of the reason for prescribing an immunosuppressant. We also note some medications may have an immunosuppressant effect, even though they are not prescribed principally to suppress the immune system. We believe, in these circumstances, eradicating oral or dental infection prior to beginning a medication that has been found to have a suppressant effect on that part of the immune system required to eradicate infectious agents could be necessary to the clinical success of the medication therapy.

Similarly, in joint replacement surgery (such as total hip and knee arthroplasty surgery) we believe there may be risks to the outcome of the procedure if an oral infection is not treated. There is evidence that some joint replacement patients have significant dental pathology found before their surgery.[79] Given the incidence of dental pathology in joint replacement patients, there may be some joint replacement patients who would experience a clinically significant benefit from a pre-operative dental exam and medically necessary treatment of oral pathology(ies). As in transplant surgery, patients having joint replacement surgery are at risk for surgical site infection, and there may be an increased risk for those patients with significant dental pathology. The presence of an overlooked oral infection may increase the risk for acute and chronic surgical site infection.[80] [81]

We acknowledge there is other clinical evidence that does not support the need for a dental exam and necessary treatment prior to total joint replacement surgery, specifically total hip and knee arthroplasty.[82] [83] Rather, there is evidence that further study is needed to determine whether pre-operative dental exams and treatments are necessary and clinically beneficial.[84] Therefore, we are interested in public comment providing systematic clinical evidence as to whether there is an inextricable link between dental service(s) and joint replacement surgery such that the dental services are substantially related and integral to the clinical success of the surgical procedures. We note that if we receive compelling clinical evidence, we may finalize in this final rule additional clinical scenarios, such as dental services prior to joint replacement surgery (for example, total hip and knee arthroplasty surgery), where payment could be made under Medicare Part A or Part B. We are seeking comment on whether there is a significant quality-of-care detriment if certain dental services are not provided prior to joint replacement surgery (such as total hip and knee arthroplasty surgery), and if so, we request a description of that systematic evidence. Specifically, we are looking for medical evidence that

[79] *https://www.aaos.org/aaosnow/2011/feb/clinical/clinical2/.*

[80] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919067/.*

[81] *https://www.nebh.org/blog/why-its-a-good-idea-to-see-a-dentist-before-your-joint-replacement/.*

[82] Barrere S, Reina N, Peters OA, Rapp L, Vergnes JN, Maret D. Dental assessment prior to orthopedic surgery: A systematic review. Orthop Traumatol Surg Res. 2019 Jun;105(4):761–772. doi: 10.1016/j.otsr.2019.02.024. Epub 2019 May 3. PMID: 31060914.

[83] Young, H., Hirsh, J., Hammerberg, E.M., & Price, C.S. (2014). Dental disease and periprosthetic joint infection. The Journal of bone and joint surgery. American volume, 96(2), 162–168. *https://doi.org/10.2106/JBJS.L.01379.*

[84] *https://www.sciencedirect.com/science/article/pii/S1877056819301318.*

the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the skeletal structure. Evidence needs to be clinically meaningful and represent a material difference that results in some level of persistence in the clinical success of the procedure to support that pre-operative dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore in connection with, and substantially related and integral to that primary covered medical service. If commenters are able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to joint replacement procedures such as total hip and knee arthroplasty surgery would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the joint replacement surgery.

We also believe there may be other clinical scenarios involving dental services that we have not yet considered, where certain dental services may be similarly inextricably linked to, and substantially related and integral to the clinical success of, certain otherwise covered medical service such that the exclusion under section 1862(a)(12) of the Act would not apply. For example, we are proposing to codify current policy that Medicare payment can be made for the wiring of teeth when done in connection with the reduction of a jaw fracture. We request comment on whether there are other dental services associated with stabilizing and/or repairing the jaw after accidental injury or trauma and similarly that similarly would not be subject to the exclusion under section 1862(a)(12) of the Act, and for which we should consider providing Medicare payment.

We solicit comment on our current approach to payment for dental services that we have already identified under our current and proposed policies as inextricably linked to, and substantially related and integral to the clinical success of, certain covered services, as well as those services we may yet identify, and other operational topics we should consider further. We acknowledge that there may be other clinical circumstances we have not yet identified where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. There may be other clinical scenarios involving physiologic or anatomic conditions in which dental services could be a medically critical precondition to the clinical success of other services, such as certain surgical procedures or cancer treatments. For these reasons, we solicit comment on whether there are other clinical scenarios for medical or surgical services where the standard of care is such that the performance of certain dental services (for example, an exam, and certain diagnostic and treatment services) is considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment, and therefore may be similarly inextricably linked to, and substantially related and integral to the clinical success of, a certain covered service, and therefore, not subject to the exclusion under section 1862(a)(12) of the Act. If we were to finalize our proposed policies as discussed under sections II.L.2.a. and II.L.2.b. of this proposed rule, we may consider finalizing, based on our review of public comments, these additional examples of dental services that may not be subject to the payment exclusion under section 1862(a)(12) of the Act because they are similarly inextricably linked to, and substantially related and integral to the clinical success of, covered medical services. If we were to finalize such additional examples of dental services, we would list those services as examples under the regulation at § 411.15(i)(3), as discussed in section II.L.2.c. of this proposed rule. Lastly, as discussed above, we recognize that the dental services we have identified for which Medicare payment could be made under our proposed policies would occur either prior to, or contemporaneously with, the covered medical service. We are also interested in comments on whether, on the same basis, there are clinical circumstances under which Medicare payment could be made for dental services furnished after the covered medical procedure or treatment.

ii. Establishment of a Process To Consider Additional Clinical Scenarios for Future Updates

As discussed, we believe there may be clinical scenarios where dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. We believe there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on this basis. To ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we believe it may be appropriate to establish a process whereby interested parties can share recommendations for our consideration, review and analysis for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3) through future rulemaking. If an interested party believes that there is a clinical scenario in which certain dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we invite interested parties to submit information about the clinical scenario and the medical evidence to support that the standard of care for the medical service is such that one would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially compromised, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. The interested party should explain why the particular dental services should not be subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act, because they are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, and provide the medical evidence to support that conclusion.

To ensure a thorough review can occur, we encourage interested parties to include relevant medical literature, clinical guidelines or generally accepted standards of care, and other supporting documentation to support our review and consideration of the clinical scenario involving dental services. To facilitate our consideration of interested parties' recommendations within an annual rulemaking cycle, we would

request that interested parties submit this information by February 10th of that year at *MedicarePhysicianFee Schedule@cms.hhs.gov.* Submissions received outside of the public comment period for a PFS proposed rule will be considered for possible inclusion in future notice and comment rulemaking cycles. Recommendations received by February, 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. For example, information received by February 10, 2024 would be reviewed for consideration and potential inclusion within the CY 2025 PFS proposed rule. We encourage interested parties to engage with us and provide medical evidence to support their recommendations for additional clinical scenarios where dental services may not fall within the scope of the payment preclusion under section 1862(a)(12) of the Act.

As discussed previously, we may consider finalizing a change, after reviewing public comments, in the CY 2023 PFS final rule to revise the list of examples of dental services for which Medicare payment can be made. Furthermore, we solicit feedback on: (1) whether there are additional clinical circumstances we should consider where dental services are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services; and (2) the establishment of a process to review additional clinical scenarios identified by the public, which we may consider finalizing, after review of public comments received, in this final rule.

iii. Request for Comment on Dental Services Integral to Covered Medical Services Which Can Result in Improved Patient Outcomes

As described in section II.L.2 of this proposed rule, we believe there are clinical scenarios where the standard of care is such that there is an immediate need for certain dental services as the necessary clinical prerequisite to an otherwise covered medical service. We believe there may be other clinical scenarios, however, where the ongoing disease management of the patient receiving the medically necessary procedure may have an improved outcome or see a clinical benefit from the performance of dental services, but that the dental service may not be inextricably linked to, or substantially related and integral to the clinical success of, the otherwise covered medical service.

For example, we believe there may be certain circumstances where the clinical benefit of medical care or treatment of a diabetic patient could be improved if certain dental services are furnished. We are interested in public feedback on whether certain dental services (for example, a dental exam, necessary treatment of a dental condition such as the extraction of an infected and mobile tooth) should be considered so integral to the standard of care for an otherwise covered medical service that the preclusion on Medicare payment under section 1862(a)(12) of the Act does not apply.

Additionally, we are interested in comments on whether the success of a given surgery is dependent upon eradication of dental or oral infection. As noted in section II.L.2.c., we believe surgeries dealing with organ transplants, cardiac valve replacement, or valvuloplasty procedures may require a dental exam and treatment prior to the surgery because the services to identify and eradicate dental or oral infection are inextricably linked to, and substantially related and integral to the success of, these otherwise covered medical services. However, we are interested in feedback on whether there are other types of surgery for which certain dental services would meet this threshold. We invite public comment on whether there are other clinical scenarios involving acute or chronic conditions that would have an improved patient outcome if dental services are furnished, and if so, whether we should consider these services as inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services.

3. Request for Comment on Other Potentially Impacted Policies

As discussed in section II.L.2.a–b of this proposed rule, we are proposing to codify and clarify our current payment policies for dental services. We recognize that under these policies there may be instances where multiple health care providers may need to coordinate the performance of certain medical and dental services based on the patients' chronic conditions and/or serious illnesses. We continue to consider improvements to our payment policies for care management services as health care delivery models evolve. As such, we seek comment on whether our current policies for care management services make clear that time spent by physicians or non-physician practitioners coordinating care with dentists regarding the performance and outcomes of services as proposed under section II.L.2 of this proposed rule, may be counted for purposes of applicable care management codes. We are also interested in whether existing care management codes adequately describe and account for time spent coordinating with dentists and their clinical staff. We are also interested in comments regarding the impact of changes in how health care is delivered, and whether an increased integration and coordination of care among health care providers should also be taken into account in considering dental services that may be inextricably linked to, and substantially related and integral to the clinical success of, a primary medical service. Additionally, we are interested in whether, and to what extent, the proposed policies as described in section II.L.2 of this proposed rule would address any inequitable distribution of dental services for Medicare beneficiaries.

Finally, we recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan or other plan offering. If we were to finalize in the CY 2023 PFS final rule our proposed policies as described further in section II.L.2 of this proposed rule, we seek comment on how current coordination of dental benefits operates, and where improvements could be provided. Additionally, we seek comment on what aspects of coordinating benefits among supplemental dental providers we should consider if we were to finalize the proposed policies as specified under section II.L.2 of this proposed rule.

4. Request for Comment on Potential Future Payment Models for Dental and Oral Health Care Services

Our waiver authority under section 1115A(d)(1) of the Act provides broad authority for the Secretary to waive such requirements of title XVIII of the Act, which pertain to Medicare, as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

In 2014, the Health Care Innovation Awards (HCIA) Round 2, a limited time grant initiative, included awards with the goal to improve the health of populations through activities focused on engaging beneficiaries, prevention, wellness, and comprehensive care that extended beyond the clinical service delivery setting. Several participants used their HCIA Round 2 funds to test models of clinical care that included payment for dental and oral care services. For further information regarding the success of these awards as applied to dental and oral care services please review the HCIA Round 2 Final

Awardee Evaluation Report (2014-2018).[85]

We are seeking comment on additional ways to integrate the payment for dental and oral health care services within existing and future payment models using the Innovation Center's waiver authority in existing or future service delivery models, including models focused on equity, care coordination, total cost of care and specific disease conditions.

M. Rebasing and Revising the Medicare Economic Index (MEI)

1. Background

The Medicare Economic Index (MEI) is authorized under section 1842(b)(3) of the Act, which relates to the reasonable charge-based payment methodology that was in place for physicians' services prior to the PFS. That section states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. CMS began calculating the MEI for this purpose on July 1, 1975, and continues to do so today for several statutory and other purposes. The MEI reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services.

The MEI is a fixed-weight input price index comprised of two broad categories: (1) Physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, private nonfarm business total factor productivity (previously referred to as multifactor productivity).[86] The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.

The current form of the MEI was described in the November 25, 1992 **Federal Register** (57 FR 55896) and was based in part on the recommendations of a Congressionally-mandated meeting of experts held in March 1987. Since that time, the MEI has been updated or revised on five instances. First, the MEI was rebased in 1998 (63 FR 58845), which moved the cost structure of the index from 1992 data to 1996 data. Second, the methodology for the productivity adjustment was revised in the CY 2003 PFS final rule with comment period (67 FR 80019) to reflect the percentage change in the 10-year moving average of economy-wide private nonfarm business total factor (multifactor) productivity. Third, the MEI was rebased in the CY 2004 PFS final rule with comment period (68 FR 63239), which moved the cost structure of the index from 1996 data to 2000 data. Fourth, the MEI was rebased in 2011 (75 FR 73262), which moved the cost structure of the index from 2000 data to 2006 data. Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74264), the MEI cost share weights were revised based on recommendations from the MEI technical advisory panel (MEI-TAP). From May 2012 through September 2012, the MEI Technical Advisory Panel conducted a technical review of the MEI, including analyses of the inputs, input weights, price-measurement proxies, and productivity adjustment. Details regarding the Panel's work and documents such as transcripts, meeting summaries, presentations, and the final report with recommendations to the Secretary of Health and Human Services are available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP* and in the FY 2014 PFS proposed rule (78 FR 43311) which provides details related to how the MEI TAP panel recommendations were implemented into the revised 2006-based MEI. The current 2006-based MEI relies on data collected from the American Medical Association (AMA) for self-employed physicians from the Physician Practice Information Survey (PPIS). The AMA has not fielded another survey since that 2006 data collection effort and so the MEI has continued to be based on 2006-based costs. In its August 28, 2012 report, the MEI–TAP expressed concern regarding the representativeness and availability of data to support the MEI, and provided two recommendations regarding the data sources to update the MEI in the future. Recommendation 2.1 stated that CMS should research whether using self-employed physician data for the MEI cost weights continues to be the most appropriate approach given the trend toward larger, physician-owned practices, as well as movement from physician-owned practices toward hospital-owned practices. Recommendation 2.2 stated that CMS should scan for and research additional data sources that may allow for more frequent updates to the MEI's cost categories and their respective weights.[87]

Updates to the PFS conversion factor (CF) were previously calculated based on a prescribed statutory formula that used a combination of the MEI and a ''sustainable growth rate''; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 115–05, April 16, 2015) repealed the previous statutory update formula and specified the update adjustment factors for calendar years 2015 and beyond. Therefore, effective beginning for CY 2015, the MEI was no longer used in calculating the annual update to the PFS CF. The annual growth in the MEI continues to be used to update the following: the Medicare telehealth originating site facility fee under section 1834(m)(2)(B)(i) of the Act, the KX Modifier Thresholds (formerly the therapy caps) under section 1833(g)(2) of the Act, targeted medical review (MR) threshold amounts (beginning in 2029) under section 1833(g)(7)(B)(ii) of the Act, Rural Health Clinic Payment Limits under section 1833(f)(2) of the Act, and the annual update to the non-drug portion of the Opioid Treatment Program payment as finalized in the CY 2020 PFS final rule (84 FR 62668 and 62669).

While the MEI annual percentage change increase is not directly used in determining the update to the PFS CF, the MEI cost weights have historically been used to update the GPCI cost share weights to weigh the four components of the practice expense GPCI (employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses), as discussed in detail in section II.G. of this proposed rule, and to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs, as discussed in section II.B. and section VII. of this proposed rule. The most recent recalibration was done for the CY 2014 RVUs, when the MEI was last

[85] *https://innovation.cms.gov/data-and-reports/2020/hcia2-fg-finalevalrpt.*

[86] *https://www.bls.gov/news.release/prod5.nr0.htm.*

[87] The MEI–TAP's final report, including all findings and recommendations, are available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.*

updated. As described in the CY 2014 PFS final rule (78 FR 74236 through 74237, and 74241), in steps 3 and 10, we adjusted the aggregate pool of PE costs in proportion to the change in the PE share in the revised MEI cost share weights. These adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275). Therefore, we believe that the MEI cost weights need to be updated to reflect more current market conditions faced by physicians in furnishing physicians' services, but note that we are proposing to delay the implementation of the proposed rebased and revised MEI cost weights for both PFS ratesetting and the proposed CY 2023 GPCIs. We believe that doing so will allow interested parties the opportunity to review and comment on the proposed rebased and revised MEI cost share weights discussed in section II.M. of this proposed rule and their potential impacts before we use such rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and updating the GPCIs. We refer readers to our discussion about using the proposed rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and for the purposes of updating the GPCIs for CY 2023 in sections II.B. and VII. of this proposed rule. In those sections, we discuss our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have on PFS payments. We are soliciting comments on the proposed delay and potential use of the proposed updated MEI cost weights in future years to recalibrate the RVU shares and to update the GPCI cost share weights, which were last realigned to the revised MEI weights in the CY 2014 PFS final rule (78 FR 74380 through 74391).

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of an input price index, while revising relates to other types of changes such as using different data sources, cost categories, or price proxies in the input price index. Effective with this CY 2023 PFS rulemaking cycle, we are proposing to rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership; that is, not limited to only self-employed physicians. In the following sections of this proposed rule, we detail our proposals regarding derivation of the cost categories and associated cost share weights, selection of the price proxies in the MEI, and the results of the proposed 2017-based MEI as compared to the current 2006-based MEI.

2. Developing the Cost Weights for Use in the MEI

The 2006-based MEI was last rebased in the CY 2011 PFS final rule with comment period (75 FR 73262 through 73275) and subsequently revised in the CY 2014 PFS final rule with comment period (78 FR 74264 through 74278). The proposed 2017-based MEI cost weights are derived predominantly from the annual expense data from the U.S. Census Bureau's Services Annual Survey (SAS, *https://www.census.gov/programs-surveys/sas.html*). Other data sources that were considered and analyzed as potential sources of expense data for Physician Offices included the BEA Benchmark Input-Output data, the Internal Revenue Services (IRS) Statistics of Income data for sole proprietors, and Medical Group Management Association (MGMA) cost and revenue data. While each of these data sources provided information on physician input price expenses, we found the SAS data to be the most technically appropriate data source available based on various factors including public availability, level of detail of expense categories, and sample representativeness of the universe. The SAS data are publicly available data that provide annual receipts estimates for the service industries. Collected data include sources of revenue and expenses by type for selected industries and selected industry-specific items. Specifically, we propose to use the 2017 SAS data from Table 5, Estimated Selected Expenses for Employer Firms for NAICS 6211 (Office of Physicians). The survey data collection in 2018 and 2019 were scaled back and therefore, data by expense category was limited. For example, the SAS expense data for lease and rental payments, professional and technical services, repair and maintenance services, and detailed utility cost were unavailable in 2018 and 2019. The 2020 data included a return to the more comprehensive collection of expense data; however, the presence of the PHE for COVID–19 raised questions regarding the representativeness and stability of the data given impacts on the utilization of physicians' services and associated expenses. Therefore, we propose to use the 2017 SAS data for the proposed 2017-based MEI because it is the most recently available and complete data.

We are proposing to supplement the 2017 SAS expense data by using several data sources for further disaggregation of compensation costs and all other residual costs, including: the 2017 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), the 2012 Bureau of Economic Analysis (BEA) Benchmark Input-Output data (I/O), the 2006 AMA PPIS, and the 2020 AMA Physician Practice Benchmark Survey. Table 30 lists the set of mutually exclusive and exhaustive cost categories and weights for the proposed 2017-based MEI compared to the 2006-based MEI.

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TABLE 30: Proposed 2017-based MEI and 2006-based MEI Cost Categories and Weights

Cost Category	Proposed 2017-based	Current 2006-based
MEI Total	**100.000%**	**100.000%**
Physician Compensation	**47.261%**	**50.866%**
Wages and Salaries	39.226%	43.641%
Benefits	8.034%	7.225%
Practice Expense	**52.739%**	**49.134%**
Non-physician Compensation	**24.716%**	**16.553%**
Non-physician Wages	**20.514%**	**11.885%**
Non-health, Non-physician Wages	12.306%	7.249%
Professional and Related	1.381%	0.800%
Management	2.171%	1.529%
Clerical	7.947%	4.720%
Services	0.807%	0.200%
Health related, Non-physician Wages	8.208%	4.636%
Non-physician Benefits	**4.202%**	**4.668%**
Other Practice Expense	**28.024%**	**32.582%**
Utilities	0.366%	1.266%
All Other Products	2.055%	2.478%
Telephone	0.471%	1.501%
Postage	-	0.898%
All Other Professional Services	**13.914%**	**8.095%**
Professional, Scientific, and Tech. Services	6.350%	2.592%
Administrative & Waste Services	2.341%	3.052%
All Other Services	5.223%	2.451%
Capital	**7.748%**	**10.310%**
Fixed Capital	5.527%	8.957%
Moveable Capital (including medical)	2.221%	1.353%
Professional Liability Insurance	**1.398%**	**4.295%**
Medical Equipment	-	1.978%
Medical Supplies	2.071%	1.760%

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Total costs equal the sum of the costs for Physician Compensation and Practice Expenses. The development of the cost weights for each cost category in the proposed 2017-based MEI is described, in detail, as follows.

a. Physician's Compensation

The component of the MEI that reflects physician work is represented by the estimated portion of compensation expenses attributable to physicians. The proposed 2017 cost weight associated with the physician's work (otherwise referred to as the Physician Compensation cost weight) is based on the estimated share of 2017 SAS expenses for total compensation associated with physician compensation. Since the compensation expense in the SAS data is only reported as an aggregate for all employees, we propose to split the compensation expenses between physicians (including nonphysician practitioners that can bill independently such as nurse practitioners (NPs), physician assistants (PAs), and other clinical personnel) and all other workers using the following process.

Step 1: Total compensation costs are calculated by summing the reported expenses in the SAS for gross annual payroll, employer costs for fringe benefits (including health insurance, defined benefit and defined contribution plans, payroll taxes, employer paid insurance premiums, and all other benefits), and temporary staff and leased employees as reported in the 2017 SAS data for NAICS 6211 (Office of Physicians).

Step 2: Determine the ratio of physician (including nonphysician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) wage costs to total wage costs. This ratio is calculated using data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) May 2017 National Industry-Specific Occupational Employment and Wage Estimates for Offices of Physicians (NAICS 6211). This data reports the number of employees by occupational category based on the Standard Occupational Classification System (SOC) and the mean hourly wage for each occupation. For each occupation, we multiply the number of employees by the mean hourly wage to estimate the total mean hourly wage expense. The sum of each occupation category represents total mean hourly wage expenses for all occupations in NAICS 6211. Then to derive the total mean hourly wage expenses for physicians (including nonphysician practitioners that can bill independently such as NPs, PAs, and other clinical personnel) we sum the following occupations: Physicians and Surgeons (29–1060); Chiropractor (29–1011); Optometrist (29–1041); Podiatrist (29–1081); Physical Therapist (29–

1123); Dieticians & Nutritionists (29–1031); Physician Assistants (29–1071); Nurse Practitioners (29–1171); and All Other Diagnosing & Treating Occupations (29–11XX) to estimate OEWS expenses for physicians. The ratio of physician total mean hourly wage costs to total mean hourly wage costs is 63.2 percent.

Step 3: We multiply the total compensation expenses from Step 1 by the ratio determined in Step 2 to derive estimated Employed Physician Compensation Expenses, which in 2017 are estimated to account for 42.4 percent of total costs.

Next, since the expenses estimated above reflect only employed physician compensation, we propose to add an estimate of compensation costs to account for physician practice owners that are not classified as employees but instead would be included in the net income of the practice. The net income physician compensation costs are estimated by the following methodology. This amount is determined in three steps:

Step 1: Subtract total expenses from total revenue as reported in the 2017 SAS data for NAICS 6211.

Step 2: Estimate the share of owners versus employees of physician practices for 2017 based on the average share of ''owners'' for 2016 and 2018 as reported in Exhibit 1 of the 2020 AMA Physician Practice Benchmark Survey. This estimated share for 2017 is 46.5 percent (and reflects the average of the share for 2016 and 2018).

Step 3: Multiply the share determined in step 2 by the amount determined in step 1, which represents the estimated expenses for net income for owners of physician practices and are 4.845 percent of total costs in 2017.

The proposed aggregate 2017-based Physician Compensation cost weight is the sum of Employed Physician Compensation cost weight (42.416 percent) and Estimated Net Income for Physician Practice Owners cost weight (4.845 percent), or 47.261 percent. By comparison, the 2006-based Physician Compensation cost weight is 50.866 percent and reflects the net income for self-employed physicians and the expenses for nonphysician clinical staff that can bill Medicare independently. The proposed 2017-based MEI cost weight for Physician Compensation is 3.6 percentage points lower than the 2006-based MEI cost weight. This difference is due to two key factors: (1) any changes that occurred in the cost to provide physician services between 2006 and 2017, and (2) the SAS data reflects relative costs for all physician ownership practices while the 2006 AMA PPIS data reflected relative costs only for self-employed physician practices.

We propose to split the Physician Compensation cost weight into two cost categories: Physician Wages and Salaries, and Physician Benefits. The Physician Wages and Salaries cost weight is calculated by multiplying the total Physician Compensation weight by the ratio of the gross payroll to the sum of gross payroll and employer's cost for fringe benefits in the 2017 SAS data, which is 83 percent. The Physician Benefits cost weight is calculated by multiplying the total physician compensation weight by the ratio of the employee benefits to the sum of gross payroll and employer's cost for fringe benefits in the 2017 SAS data, which is 17 percent. As a result, the proposed Physician Wages and Salaries cost weight is 39.226 percent and the proposed Physician Benefits cost weight is 8.034 percent in the 2017-based MEI.

b. Practice Expenses

The Practice Expenses cost weight reflects all remaining operating costs other than physician compensation. We propose to determine the remaining Practice Expense cost weights in the 2017-based MEI using the 2017 SAS Expense data for NAICS 6211 expressed as a percentage of total costs. The explanations for the derivation of the individual cost weights under Practice Expenses are detailed below.

(1) Non-Physician Compensation

We propose to estimate the cost weight for Non-physician Compensation using the 2017 SAS data for these expenses. As mentioned previously, since the compensation expenses in the SAS data are only reported as an aggregate for all employees, we are proposing to multiply the 2017 SAS total compensation expenses for NAICS 6211 by 36.8 percent, which is the residual of the 63.2-percent share determined for physicians (including nonphysician practitioners that can bill independently such as NPs, PAs, and other clinical personnel).

Then, we multiply the total compensation expenses by the ratio of nonphysician compensation expenses to total compensation expenses. This results in the proposed Non-physician Compensation cost weight of 24.716 percent in the proposed 2017-based MEI.

Next, we propose to split the Non-physician Compensation cost weight into two cost categories: Non-physician Wages and Salaries, and Non-physician Benefits. The Non-physician Wages and Salaries cost weight is calculated by multiplying the total Non-physician Compensation cost weight by ratio of the gross payroll to the sum of gross payroll and employer's expense for fringe benefits in the 2017 SAS data, which is 83 percent. The Non-physician Benefits cost weight is calculated by multiplying the total Non-physician Compensation weight by the ratio of the employee benefits to the sum of gross payroll and employer's expenses for fringe benefits in the 2017 SAS data, which is 17 percent. As a result, the proposed Non-physician Wages and Salaries cost weight is 20.514 percent in the proposed 2017-based MEI and the proposed Non-physician Benefits cost weight is 4.202 percent. For comparison purposes, the 2006-based MEI cost weights are 11.885 percent and 4.668 percent, respectively. We are also proposing to disaggregate the Non-physician Wages and Salaries cost weight into two categories: (1) Health-related, non-physician and (2) Nonhealth, non-physician Wages and Salaries.

Of the 36.8 percent of total SAS compensation costs associated with non-physicians, 14.7 percent points are determined to be associated with The Health-related, non-physician Wages and salaries. This percentage reflects the mean hourly wages to total mean hourly wages from the 2017 OEWS data for the following occupations: Health Technologists and Technicians (29-2000); Other Healthcare Practitioners and Technical (29-9000); and Healthcare Support (31-0000). Applying this share (40 percent) to the Non-physician wages cost weight results in a proposed weight of 8.208 percent for the health-related, non-physician Wages and Salaries cost weight for the proposed 2017-based MEI.

The remaining approximately 60 percent are associated with Nonhealth, non-physician Wages and salaries (Salary 22.1 percentage points of the 36.8 percent). This percentage reflects the mean hourly wages to total mean hourly wages from the 2017 OEWS data for the following occupations: Management (11–0000); Business and Financial Operations (13–0000); Computer and Mathematical (15–0000); Architecture and Engineering (17–0000); Life, Physical, and Social Science (19–0000); Community and Social Service (21–0000); Legal (23–0000); Education, Training, and Library (25–0000); Arts, Design, Entertainment, Sports, and Media (27–0000); Protective Service (33–0000); Food Preparation and Serving Related (35–0000); Building and Grounds Cleaning and Maintenance (37–0000); Personal Care and Service (39–0000); Sales and Related (41–0000);

Office and Administrative Support (43–0000); Construction and Extraction (47–0000); Installation, Maintenance, and Repair (49–0000); Production (51–0000); and Transportation and Material Moving (53–0000). Applying this share (60 percent) to the non-physician wages cost weight results in a proposed weight of 12.306 percent for the Nonhealth, non-physician Wages and Salaries cost weight for the proposed 2017-based MEI.

Next, since the non-health, non-physician wages represent various types of occupations that may experience different wage inflation pressures, we propose to disaggregate the Non-health, non-physician Wages and Salaries cost weight of 12.306 percent into four occupational subcategories. To arrive at a distribution for these separate occupational categories (Professional Related (PR) workers, Managers, Clerical workers, and Service workers), we determined an estimate of annual earnings for each using the Standard Occupational Classification (SOC) system. The professional and related wages salaries consist of the following occupational categories: Business and Financial Operations (13–0000); Computer and Mathematical (15–0000); Architecture and Engineering (17–0000); and Life, Physical, and Social Science (19–0000). The Clerical wages salaries consist of the occupational category Office Administrative Support (43–0000). The Services wages salaries consist of the following occupational categories: Community and Social Service (21–0000); Arts, Design, Entertainment, Sports, and Media (25–0000); Protective Service (33–0000); Food Preparation and Serving Related (35–0000); Building and Grounds Cleaning and Maintenance (37–0000); Personal Care and Service (39–0000); Sales and Related (41–0000); Construction and Extraction (47–0000); Installation, Maintenance, and Repair (49–0000); Production (51–0000); and Transportation and Material Moving (53–0000).

The Non-health, non-physician Wages and Salaries cost weight of 12.306 percent is multiplied by the relative share of each category to arrive at the detailed distribution. The occupational distribution in the proposed 2017-based MEI, as well as the distribution for the 2006-based MEI is presented in Table 31.

TABLE 31: Percent Distribution of Nonphysician Wages and Salaries Cost Weights by Occupational Group: Proposed 2017-based MEI and 2006-based MEI

Cost Category	Proposed 2017-_weight	2006_weight
Non-physician wages & salaries	**20.514%**	**11.885%**
Non-health, non-physician wages & salaries	12.306%	7.249%
Professional and Related wages & salaries	1.381%	0.800%
Management wages & salaries	2.171%	1.529%
Clerical wages & salaries	7.947%	4.720%
Services wages & salaries	0.807%	0.200%
Health related, Non-physician wages & salaries	8.208%	4.636%

(2) Other Practice Expenses

We propose that the remaining aggregate Other Practice Expenses would be derived using the 2017 NAICS 6211 SAS expense data and calculated as the sum of the expenses for the detailed categories expressed as a percentage of total expenses. The aggregate Other Practice Expenses include all SAS expenses other than gross annual payroll, fringe benefits, and temporary staff and leased employee expenses. Additionally, we propose to remove the estimated expenses for drugs and separately billable supplies (which are paid outside of the PFS system) from total expenses in order to be consistent with the PFS. The Other Practice Expenses share of total costs in the proposed 2017-based MEI is 28.023 percent compared to a cost weight of 32.582 percent in the 2006-based MEI.

We further propose to use the 2017 SAS data for NAICS 6211 to disaggregate the Other Practice Expenses into the following ten cost categories: Utilities; All Other Products; Telephone; Administrative Support & Waste Services; All Other Services; Professional, Scientific, and Technical; Fixed Capital; Moveable Capital; Professional Liability Insurance; and Medical Supplies. Table 32 shows the 10 detailed cost weights for the Other Practice Expenses for the 2017-based MEI, which is 6 fewer categories than the 2006-based MEI. The major differences are: (1) we propose to have one cost category for All Other Products in the proposed 2017-based MEI instead of having separate cost categories for Chemicals, Paper, Rubber and Plastics, and Other Miscellaneous Products as done for the 2006-based MEI, (2) we propose to eliminate the separate cost category for Postage as the cost weight was small (less than 0.2 percentage point) and include the expenses for postage in the proposed All Other Products cost weight, and (3) we propose to eliminate the cost category for Medical Equipment as the cost weight for the Moveable Capital in the proposed 2017-based MEI includes the expenses for all types of machinery and equipment, including medical equipment; we do not have a data source available to split the expenses between Medical Equipment and All Other Equipment in the SAS or I/O data.

TABLE 32: 2006-Based and Proposed 2017-Based Cost Categories and Weights for Other Practice Expenses

Cost Category	2006	Proposed 2017
Other Practice Expense	**32.582%**	**28.023%**
Utilities	1.266%	0.366%
All Other Products	2.478%	2.055%
Telephone	1.501%	0.471%
Postage	0.898%	-
All Other Professional Services	**8.095%**	**13.914%**
Professional, Scientific, and Technical Services	2.592%	6.350%
Administrative Support & Waste Services	3.052%	2.341%
All Other Services	2.451%	5.223%
Capital	**10.310%**	**7.748%**
Fixed Capital	8.957%	5.527%
Moveable Capital	1.353%	2.221%
Professional Liability Insurance	**4.295%**	**1.398%**
Medical Equipment	1.978%	-
Medical Supplies	1.760%	2.071%

As previously mentioned, we are proposing to make one adjustment to the medical supplies expenses as reported on the SAS data to exclude estimated expenses associated with drugs and separately billable supplies. We propose to make this adjustment in order to exclude the expenses that are paid outside of the PFS and to be consistent with the expenses that were also excluded in the 2006-based MEI. Finally, we propose to use the BEA 2012—Benchmark I/O data aged to 2017 to determine the split between All Other Products and All Other Services that are captured in the residual ''all other expenses'' line in the 2017 SAS data. The BEA 2012—Benchmark I/O data can be accessed at *https://www.bea.gov/industry/input-output-accounts-data#supplemental-estimate-tables.* We note that this method of splitting residual expenses is similar to the methodology used in the 2006-based MEI where the 2002 Benchmark I/O data was aged to 2006 to further disaggregate the residual expense from the AMA PPIS.

The following is a description of the types of expenses included in each of the detailed categories under Other Practice Expenses:

(a) Utilities

The proposed weight for Utilities was calculated using the 2017 SAS expense data expressed as a percentage of total expenses. Utilities expenses are calculated as the sum of the expenses from SAS for: (1) purchased electricity, (2) purchased fuels (except motor fuels), and (3) water, sewer, refuse removal, and other utility payments. The SAS survey questionnaire defines the purchased electricity expenses as costs paid for electricity. The SAS survey questionnaire defines the purchased fuels (except motor fuels) as the costs for fuel for heating, power, or generating electricity (*e.g.,* natural gas, propane, oil, coal). The SAS survey questionnaire defines the water, sewer, refuse removal, and other utility payments as the costs for hazardous waste removal. If the utility payments for any of these expenses are included with lease and rental payments then they are captured in the SAS question for lease and rental payments for land, building, structures, storage spaces, or offices. The proposed cost weight for Utilities in the 2017-based MEI is 0.366 percent.

(b) Telephone Services

The Telephone cost weight in the proposed 2017-based MEI includes 2017 SAS expenses reported for purchased communication services. The SAS survey questionnaire defines purchased communication services as telephone, cellular, and fax services; computer-related communications (for example, internet, connectivity, online), and other wired and wireless communication services. The proposed cost weight for Telephone Services is 0.471 percent.

(c) All Other Products

The proposed cost weight for All Other Products for the proposed 2017-based MEI was calculated in two steps. First, all other operating expenses are calculated as a percentage of total expenses from the 2017 SAS, which was 9.158 percent. The SAS survey questionnaire defines the All other operating expenses as operating expenses not reported or captured by any other survey expense question or specifically excluded in the general instructions. These expenses specifically excluded in the general instructions are: transfers made within the company, capitalized expenses, interest, bad debt, impairment, and income tax.

Second, All Other Products expenses are calculated as the estimated percentage of expenses from SAS for all other operating expenses using Benchmark I/O data. In order to split the aggregate all other operating expenses, which reflects both products and services, we propose to rely on the 2012 Benchmark I/O data for NAICS 6211, Offices of Physicians aged to 2017 for the NAICS categories that align with expenses in the SAS all other operating expenses. The process for doing this is explained step by step as follows:

Step 1: We crosswalked the NAICS categories in the 2012 Benchmark I/O data to the expense questions in the 2017 SAS data. This process allowed for all Benchmark I/O costs to be grouped into similar buckets as the SAS Expenses as closely as possible

Step 2: We aged the 2012 Benchmark I/O costs to 2017 for each of the following major buckets of expenses: Physician Compensation, Non-Physician Compensation, Capital-related expenses (fixed and moveable), PLI, Professional Services, Other Products, Other Services, Utilities, and Medical Supplies using the growth of

the various price proxies used for these cost categories in the 2006-based MEI.

Step 3: The share of each of the aged 2012 I/O expenses were calculated as a percentage of the total aged 2012 I/O expenses. The aged 2012 I/O categories of other products and other services were estimated to account for about 9.6 percent of total costs. This share is similar to the SAS residual cost share weight of 9.158 percent

The following Table 33 shows the Benchmark I/O NAICS categories that were crosswalked to the SAS all other operating expenses for all other product expenses.

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TABLE 33: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting All Other Products

ALL OTHER PRODUCTS	
111400	Greenhouse, nursery, and floriculture production
321100	Sawmills and wood preservation
321200	Veneer, plywood, and engineered wood product manufacturing
321910	Millwork
3219A0	All other wood product manufacturing
327100	Clay product and refractory manufacturing
327200	Glass and glass product manufacturing
327310	Cement manufacturing
327320	Ready-mix concrete manufacturing
327330	Concrete pipe, brick, and block manufacturing
327390	Other concrete product manufacturing
327910	Abrasive product manufacturing
331110	Iron and steel mills and ferroalloy manufacturing
331200	Steel product manufacturing from purchased steel
332310	Plate work and fabricated structural product manufacturing
332710	Machine shops
332720	Turned product and screw, nut, and bolt manufacturing
339920	Sporting and athletic goods manufacturing
311513	Cheese manufacturing
31161A	Animal (except poultry) slaughtering, rendering, and processing
311810	Bread and bakery product manufacturing
311910	Snack food manufacturing
311920	Coffee and tea manufacturing
312110	Soft drink and ice manufacturing
313200	Fabric mills
314900	Other textile product mills
315000	Apparel manufacturing
316000	Leather and allied product manufacturing
322120	Paper mills
322130	Paperboard mills
322299	All other converted paper product manufacturing
324121	Asphalt paving mixture and block manufacturing
324122	Asphalt shingle and coating materials manufacturing
325120	Industrial gas manufacturing
325130	Synthetic dye and pigment manufacturing
325180	Other Basic Inorganic Chemical Manufacturing
325190	Other basic organic chemical manufacturing
325510	Paint and coating manufacturing
325520	Adhesive manufacturing
325610	Soap and cleaning compound manufacturing
3259A0	All other chemical product and preparation manufacturing
326110	Plastics packaging materials and unlaminated film and sheet manufacturing
326120	Plastics pipe, pipe fitting, and unlaminated profile shape manufacturing
326140	Polystyrene foam product manufacturing
326150	Urethane and other foam product (except polystyrene) manufacturing
326160	Plastics bottle manufacturing
326190	Other plastics product manufacturing
326210	Tire manufacturing
425000	Wholesale electronic markets and agents and brokers
491000	Postal service

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Step 4: The share of expenses for the aged 2012 Benchmark I/O all other products to the aged total all other operating expenses in the Benchmark I/O were calculated. This resulted in products accounting for 22.4 percent and services accounting for 77.6 percent of the I/O expenses classified as all other costs. We then multiplied the SAS all other operating expenses (9.158 percent) by 22.4 percent to estimate expenses for the all other products .

Step 5: Lastly, we divided the estimated all other products SAS expenses by the total SAS expenses and the resulting proposed 2017-based MEI cost weight for All Other Products is 2.055 percent.

(d) Administrative Support and Waste Services

The proposed weight for Administrative Support and Waste for the proposed 2017-based MEI is based on a portion of the 2017 SAS all other operating expenses (Residual). Similar to the methodology to calculate the All Other Products cost weight we follow a similar process for the Administrative Support Waste Services cost weight and the All Other Services cost weight discussed in the next section. First, we estimated the total SAS residual expenses associated with other services by multiplying the SAS all other operating expenses by 77.6 percent, or a cost weight of 7.103 percent accounting for the SAS residual expenses associated with services rather than products.

Next, we carved out a portion of these all other services expenses that we identified as Administrative Support and Waste Services from the I/O categories as shown in Table 34 below. These categories accounted for about 26 percent of All other operating expenses. Finally, we divided the estimated Administrative Support and Waste Services expenses by the Total SAS Expenses and the resulting proposed 2017-based MEI cost weight for Administrative Support and Waste Services is 2.341 percent.

TABLE 34: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting Administrative Support & Waste Services

ADMINISTRATIVE SUPPORT & WASTE	
492000	Couriers and messengers
533000	Lessors of nonfinancial intangible assets
561700	Services to buildings and dwellings
561100	Office administrative services
561200	Facilities support services
561400	Business support services
561500	Travel arrangement and reservation services
561600	Investigation and security services
561900	Other support services
813B00	Civic, social, professional, and similar organizations

(e) All Other Services

The proposed weight for All Other Services for the proposed 2017-based MEI was determined in two steps. First, as was done for other products, we identified I/O categories (as shown in Table 35) associated with other services that would crosswalk to the 2017 SAS data for all other operating expenses. Next, we carved out a portion of these all other services expenses that were not assigned to Administrative Support and Waste Services from the I/O categories, the categories assigned to all other services are shown in Table 35. Using this information, we determined that All Other Services accounted for 52 percent of the SAS expenses for other operating expenses, or a weight of 4.762 percent.

TABLE 35: Crosswalk of Benchmark I/O NAICS Commodity Codes to SAS All Other Operating Expenses Reflecting All Other Services

ALL OTHER SERVICES	
481000	Air transportation
484000	Truck transportation
485000	Transit and ground passenger transportation
486000	Pipeline transportation
48A000	Scenic and sightseeing transportation and support activities for transportation
493000	Warehousing and storage
511110	Newspaper publishers
511120	Periodical Publishers
511130	Book publishers
5111A0	Directory, mailing list, and other publishers
512100	Motion picture and video industries
5191A0	News syndicates, libraries, archives and all other information services
522A00	Nondepository credit intermediation and related activities
52A000	Monetary authorities and depository credit intermediation
523900	Other financial investment activities
523A00	Securities and commodity contracts intermediation and brokerage
524113	Direct life insurance carriers
711100	Performing arts companies
711200	Spectator sports
711500	Independent artists, writers, and performers
711A00	Promoters of performing arts and sports and agents for public figures
713900	Other amusement and recreation industries
722110	Full-service restaurants
722211	Limited-service restaurants
722A00	All other food and drinking places
812300	Dry-cleaning and laundry services
812900	Other personal services

Second, we also propose to include the expenses directly reported on the SAS survey for purchased repairs and maintenance to machinery and equipment in the other services category. The SAS survey questionnaire defines these expenses to include expensed repair and maintenance services to machinery, vehicles, equipment, and computer hardware. These expenses accounted for 0.461 percent of total expenses, and when added to the 4.762 percent calculated above, results in a proposed 2017-based MEI cost weight for All Other Services of 5.223 percent.

(f) Professional, Scientific, and Technical Services

The Professional, Scientific and Technical Services cost weight includes the sum of the 2017 SAS expenses for three categories: (1) data processing and other purchased computer services, (2) purchased advertising and promotional services, and (3) purchased professional and technical services. The SAS survey questionnaire defines data processing and other purchased computer services to include expenses for web hosting, computer facilities management services, computer input preparation, data storage, computer time rental, optical scanning services, and other computer-related advice and services (including training). The SAS survey questionnaire defines purchased advertising and promotional services to include marketing and public relations services. The SAS survey questionnaire defines purchased professional and technical services to include management consulting, accounting, auditing, bookkeeping, legal, actuarial, payroll processing, architectural, engineering, and other professional services. The cost weight for Professional, Scientific, and Technical Services is 6.350 percent in the proposed 2017-based MEI.

(g) Fixed Capital

The Fixed Capital cost weight includes the sum of the 2017 SAS expenses for four categories: (1) purchased repairs and maintenance to buildings, structures, and offices, (2) lease and rental payments for land, buildings, structures, store spaces, and offices, (3) an estimated portion of depreciation and amortization charges, and (4) governmental taxes and license fees. The SAS survey questionnaire defines purchased repairs and maintenance to buildings, structures, and offices as repair and maintenance to integral parts of buildings (for example, elevators, heating systems). The SAS survey questionnaire defines lease and rental payments for land, buildings, structures, store spaces, and offices to include the rental or lease expenses paid for these items including any penalties incurred for broken leases. The SAS survey questionnaire defines depreciation and amortization charges to include depreciation charges taken against tangible assets owned and used by this firm, tangible assets owned and used by this firm within leaseholds, tangible assets obtained through capital lease agreements, and amortization charges against intangible assets (patents, copyrights). We propose to include the share of the depreciation expenses applicable to only the structures by multiplying the total

depreciation expenses by the share of total lease and rental payments that were associated with land, buildings, structures, store spaces, and offices as reported on the SAS, which is 89 percent. The SAS survey question defines governmental taxes and license fees as payments to government agencies for taxes and licenses including business and property taxes. The proposed cost weight for Fixed Capital for the proposed 2017-based MEI is 5.527 percent.

(h) Moveable Capital

The Moveable Capital cost weight includes the sum of the 2017 SAS expenses for five categories: (1) expensed equipment, (2) expensed purchases of other materials, parts, and supplies, (3) expensed purchases of software, (4) an estimated portion of depreciation and amortization charges, and (5) lease and rental payments for machinery, equipment, and other tangible items. The SAS survey questionnaire defines expensed equipment as expensed computer hardware and other equipment (for example, copiers, fax machines, phones, shop and lab equipment, CPUs, monitors). The SAS survey questionnaire defines depreciation and amortization charges to include depreciation charges taken against tangible assets owned and used by this firm, tangible assets owned and used by this firm within leaseholds, tangible assets obtained through capital lease agreements, and amortization charges against intangible assets (patents, copyrights). We propose to include the share of the depreciation expenses applicable to only the machinery equipment by multiplying the total depreciation expenses by the share of total lease and rental payments associated with machinery equipment as reported on the SAS, which is 11 percent. The SAS survey question defines lease and rental payments for machinery, equipment, and other tangible items as lease and rental of transportation equipment without operators including penalties incurred for broken lease agreements. The proposed cost weight for Moveable Capital for the proposed 2017-based MEI is 2.221 percent.

(i) Professional Liability Insurance (PLI)

The Professional Liability Insurance (PLI) cost weight includes 2017 SAS expenses reported for professional liability insurance. The SAS survey questionnaire defines professional liability insurance as the premiums paid for professional liability insurance and the amounts set aside for self-insurance. The proposed cost weight for PLI is 1.398 percent in the proposed 2017-based MEI.

(j) Medical Supplies

The Medical Supplies cost weight includes 2017 SAS expenses reported for Medical supplies with an adjustment to remove the estimated expenses for drugs and separately billable medical supplies. The SAS survey questionnaire defines medical supplies as the materials and supplies used to provide medical services to others (except for medical equipment). Since the reported expenses in the SAS would include the expenses for drugs and biologicals, as well as the expenses for supplies that generally are paid separately under Medicare we propose to remove the expenses for these two items from the SAS expenses reported using the following methodology:

Step 1: To remove the separately billable drug expenses, we rely on the reported expenses for separately billable drugs from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for separately billable drugs to 2017 using the growth in Medicare Part B physician-administered drug spending. Using this method, we inflate the 2006 AMA PPIS expenses for separately billable drugs to 2017 by an increase factor of 1.784 (or 78.4 percent).

Step 2: To remove the non-separately billable drug expenses, we rely on a similar method where we start with the reported expenses for non-separately billable drugs from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for non-separately billable drugs to 2017 using the growth in the PPI for prescription drugs. Using this method, we inflate the 2006 AMA PPIS expenses for non-separately billable drugs to 2017 by an increase factor of 2.122 (or 112.2 percent).

Step 3: To remove the non-separately billable supply expenses, we start with the reported expenses for non-separately billable supplies from the 2006 AMA PPIS data. We inflate the reported AMA PPIS expenses for non-separately billable supplies to 2017 using the growth in the Medical supplies price proxy in the 2006-based MEI (a 50/50 blend of the PPI—Commodity—Medical and surgical appliances and supplies and the CPI—Medical equipment and supplies). Using this method, we inflate the 2006 AMA PPIS expenses for non-separately billable supplies to 2017 by an increase factor of 1.048 (or 4.8 percent).

Step 4: We then calculate the share of estimated 2017 expenses for all drugs and separately billable supplies from steps 1-3 as a percentage of total drugs and medical supplies expenses from the 2017 SAS for NAICS 6211. This share is 80 percent.

Step 5: We multiply the SAS 2017 total medical supplies expenses by a factor of 0.2 (or $1-0.8$) in order to estimate the 2017 SAS expenses for non-separately billable medical supplies only.

Taking the 2017 estimated expenses for non-separately billable medical supplies as a ratio of total expenses as reported on the 2017 SAS for NAICS 6211 results in a proposed Medical Supplies cost weight of 2.071 percent in the proposed 2017-based MEI.

3. Selection of Price Proxies for Use in the MEI

To select prices proxies for the proposed 2017-based MEI cost categories, most of the proxy measures we considered are based on BLS data and are grouped into one of the following four categories:

- Producer Price Indices (PPIs): PPIs measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- Consumer Price Indices (CPIs): CPIs measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available or if the particular expenditure category is likely to contain purchases made at the final point of sale.
- Employment Cost Indices (ECIs): ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC). We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:
- Reliability: Reliability indicates that the index is based on valid statistical

methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

• Timeliness: Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market basket levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

• Availability: Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

• Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied. In this rule, we present a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing to use for the proposed 2017-based MEI (as shown in Table 36) are the same as those used in the 2006-based MEI except as noted below.

a. Physician Compensation

(1) Physician Wages and Salaries

We propose to continue to use the ECI for Wages and Salaries for Professional and Related Occupations (Private Industry) (BLS series code CIU2020000120000I) to measure price growth of this category in the proposed 2017-based MEI. We believe this price proxy reflects the wage pressures faced by physicians in that it captures wage trends in labor markets of skilled professional workers without being directly affected by trends in physician income that may be influenced by the ownership structure of physician practices. This price proxy also follows the recommendation of the MEI-TAP that the price proxy would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled ''Social Security Amendments of 1972,'' which stated that the index should reflect changes in practice expenses and ''general earnings''. This is the same proxy used in the 2006-based MEI.

(2) Physician Benefits

We propose to continue to use the ECI for Benefits for Professional and Related Occupations (Private Industry) to measure price growth of this category in the proposed 2017-based MEI. The ECI for Benefits for Professional and Related Occupations is derived using BLS's Total Compensation for Professional and Related Occupations (BLS series ID CIU2010000120000I) and the relative importance of wages and salaries within total compensation. We believe this series is technically appropriate because it better reflects the benefit trends for professionals requiring advanced training. This is the same proxy used in the 2006-based MEI.

b. Practice Expense

(1) Non-Physician, Non-Health-Related Wages and Salaries

• Professional and Related: We propose to continue using the ECI for Wages and Salaries for Professional and Related Occupation (Private Industry) (BLS series code CIU2020000120000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

• Management: We propose to continue using the ECI for Wages and Salaries for Management, Business, and Financial (Private Industry) (BLS series code CIU2020000110000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

• Clerical: We propose to continue using the ECI for Wages and Salaries for Office and Administrative Support (Private Industry) (BLS series code CIU2020000220000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

• Services: We propose to continue using the ECI for Wages and Salaries for Service Occupations (Private Industry) (BLS series code CIU2020000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(2) Non-Physician, Health-Related Wages and Salaries

We propose to continue to use the ECI for Wages and Salaries for Hospital Workers (Private Industry) (BLS series code CIU2026220000000I) to measure the price growth of this cost category in the proposed 2017-based MEI. The ECI for Hospital workers has an occupational mix that approximates that of physicians' offices. This is the same proxy used in the 2006-based MEI.

(3) Non-Physician Benefits

We propose to continue using a composite ECI for non-physician employee benefits in the proposed 2017-based MEI. The weights and price proxies for the composite benefits index are shown in Table 36, which lists the five ECI series and corresponding weights used to construct the proposed composite benefit index for nonphysician employees in the proposed 2017-based MEI. We note the ECI benefits series are derived based on BLS published data from the applicable Total Compensation ECI and Wages & Salaries ECI as BLS does not publish the ECI Benefit Indexes directly.

TABLE 36: Proposed 2017-based Composite Benefits Blend Cost Weights

	Price Proxy	2017	2006
Non-Health, Non-physician Benefits		**60%**	**61%**
Professional and Related	ECI - Benefits for Private industry workers in Professional and related	7%	7%
Management	ECI - Benefits for Private Industry workers in Management, Business, and Financial	10%	13%
Clerical	ECI - Benefits for Private Industry workers in Office and Administrative Support	39%	40%
Services	ECI - Benefits for Private Industry workers in Service Occupations	4%	2%
Health related, non-physician Benefits	ECI - Benefits for All Civilian workers in Hospitals	**40%**	**39%**

(4) Other Practice Expense

(a) Utilities

We propose to continue using the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(b) All Other Products

We propose to use the PPI—Final demand—Finished goods less foods and energy (BLS series code WPUFD413) as the price proxy for this category. We believe that the expenses that physician purchase for use in providing physicians services are better reflected by purchases at the wholesale or producer level rather than at the consumer level and the growth in overall prices less food and energy provides a good approximation for the inflation pressures experienced for these expenses. The 2006-based MEI used several PPI and CPI series to proxy the price growth for the products reflected in this category.

(c) Telephone

We propose to continue using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(d) Professional, Scientific, and Technical Services

We propose to continue to use the ECI for Total Compensation for Professional, Scientific, and Technical Services (Private Industry) (BLS series code CIU2015400000000I) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(e) Administrative and Support Services

We propose to continue to use the ECI for Total Compensation for Administrative, Support, Waste Management, and Remediation Services (Private Industry) (BLS series code CIU2015600000000I) to measure the price growth of this cost category in the 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(f) All Other Services

We are proposing to continue to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

(g) Fixed Capital

We propose to continue to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(h) Moveable Capital

We propose to continue to use the PPI for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(i) Professional Liability Insurance

Unlike the other price proxies based on data from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. The MEI–TAP discussed the methodology of the CMS PLI index, as well as considered alternative data sources for the PLI price proxy, including information available from BLS and through State insurance commissioners. As detailed in the CY 2014 PFS final rule (78 FR 74271), the MEI–TAP ''believes the current index appropriately reflects the price changes in premiums throughout the industry.'' Accordingly, we propose to continue using the CMS Physician PLI index to measure the price growth of this cost category in the proposed 2017-based MEI. This is the same proxy used in the 2006-based MEI.

(j) Medical Supplies

We propose to continue using a blended index comprised of 50/50 blend of the PPI for Surgical Appliances (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). This is the same proxy used in the 2006-based MEI.

Table 37 shows the proposed 2017-based MEI cost categories, weights and price proxies.

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TABLE 37: Proposed 2017-Based MEI Cost Categories, Weights, and Price Proxies

Proposed 2017-based Medicare Economic Index		
Cost Category	**2017**	**2017 Price Proxy**
MEI Total	**100.000%**	
Physician Compensation	**47.261%**	
Wages and Salaries	39.227%	ECI - Wages and salaries for Private industry workers in Professional and related
Benefits	8.034%	ECI - Total Benefits for Private industry workers in Professional and related
Practice Expense, including PLI	**52.739%**	
Non-physician compensation	**24.716%**	
Non-physician wages	**20.514%**	
Non-health, non-physician wages	12.306%	
Professional and Related wages	1.381%	ECI - Wages and salaries for Private industry workers in Professional and related
Management wages	2.171%	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial
Clerical wages	7.947%	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support
Services wages	0.807%	ECI - Wages and Salaries for Private Industry workers in Service Occupations
Health related, non-physician wages	8.208%	ECI - Wages and salaries for All Civilian workers in Hospitals
Non-physician benefits	**4.202%**	Composite - ECI - Total Benefits for the 5 non-physician wage categories
Other Practice Expense	**28.023%**	
Utilities	0.366%	CPI - Fuels and utilities
All Other Products	2.055%	PPI - Final demand - Finished goods less foods and energy
Telephone	0.471%	CPI - Telephone Services
All Other Professional Services	**13.914%**	
Professional, Scientific, and Technical Services	6.350%	ECI - Total compensation for Private industry workers in Professional, scientific, and technical services
Administrative support & waste	2.341%	ECI - Total compensation for Private industry workers in Office and administrative support
All Other Services	5.223%	ECI - Total compensation for Private industry workers in Service occupations
Capital	**7.748%**	
Fixed Capital	5.527%	PPI - Industry - Lessors of nonresidential buildings
Moveable Capital	2.221%	PPI - Commodity - Machinery and equipment
Professional Liability Insurance	**1.398%**	**CMS - Professional Liability Insurance Index, physicians**
Medical supplies	2.071%	Composite: PPI - Commodity - Medical and surgical appliances and supplies (50%), PPI - Commodity - Surgical and medical instruments (50%)

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4. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) total factor productivity (previously referred to as multifactor productivity) that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of economy-wide private nonfarm business labor productivity.

The MEI–TAP's Finding 5.1 states that, ''[t]he Panel reviewed the basis for the current economy-wide multifactor productivity adjustment (Private

Nonfarm Business Multifactor Productivity) in the MEI and finds such an adjustment continues to be appropriate. This adjustment prevents ''double counting'' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

We propose to continue to use the current method of applying a productivity adjustment to the full MEI increase factor in the proposed 2017-based MEI. As described in the CY 2003 PFS final rule with comment period, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We believe that using the 10-year moving average percent change in economy-wide total factor productivity is appropriate for deriving a stable measure that helps alleviate the influence that the peak (or a trough) of a business cycle may have on the measure. The adjustment will be based on the latest available historical economy-wide nonfarm business total factor productivity data as measured and published by BLS.

5. Results of Proposed Rebasing and Revising of the MEI

Table 38 illustrates the results of the proposed update to the MEI cost weights for Physician Compensation, Practice Expenses (excluding PLI), and PLI from a 2006-based cost distribution to the proposed 2017-based cost distribution, including all the proposals as specified.

TABLE 38: Percent Distribution of Major Physician Expense Components: 2006 and 2017

	Weight	
RVU Component	Current	Proposed
	2006	2017
Physician Work	50.9%	47.3%
Practice Expense	44.8%	51.3%
Malpractice or PLI	4.3%	1.4%
Total	100.0%	100.0%

Table 39 shows the average calendar year percent change for CY 2016 to CY 2023 for both the 2006-based MEI and proposed 2017-based MEI. The proposed 2017-based MEI annual percent changes differ from the 2006-based MEI annual percent changes by 0.1 to 0.2 percentage point for any given year.

TABLE 39: Annual Percent Changes in the 2006-Based and the Proposed 2017-based MEI

Update Year[1]	Proposed 2017-based MEI	2006-based MEI
2016	1.4	1.2
2017	1.3	1.1
2018	1.5	1.4
2019	1.8	1.6
2020	1.9	1.8
2021	1.7	1.5
2022	2.2	2.1
2023	3.8	3.7
Average Change	2.0	1.8

[1]Update year based on historical data through the second quarter of the prior calendar year. For example, the 2020 update is based on historical data through the second quarter 2019.

As shown in Table 39, the percent change of the proposed 2017-based MEI for the CY 2023 is an increase of 3.8 percent, one tenth of a percentage point higher than the 2006-based MEI for the same period based on the current expectation from the IGI 2022Q1 forecast with historical data through 2021Q4. The CY 2023 MEI increase factors for the 2006-based MEI and the proposed 2017-based MEI will be updated to reflect historical data available (through 2022Q2) for the CY 2023 PFS final rule.

III. Other Provisions of the Proposed Rule

A. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts §§ 414.902 and 414.940)

1. Background

Drugs and biologicals payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limit amounts for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology

in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are covered under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient.

Many drugs and biologicals (hereafter referred to as a drugs) payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often times, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for industry,[88] a single-dose container is designed for use with a single patient as a single injection or infusion. The FDA-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. When a provider must discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (Drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B in order to more effectively identify and monitor billing and payment for discarded amounts of drugs.[89] [90] The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting. Additional details about this policy can be found in Chapter 17 of the Medicare Claims Processing Manual [91] and in the JW modifier frequently asked questions (FAQ) document.[92]

Medicare Part B data for discarded amounts of drug (based on the JW modifier) have been published on the CMS website annually for calendar years beginning in 2017.[93] Data for 2020 shows that Medicare paid nearly $720 million for discarded amounts of drugs from a single-dose container or single-use package (hereafter referred to as single-dose container) paid under Part B with claims identifying the discarded amounts with the JW modifier. JW modifier data from 2020 is the most recent available at the time of this analysis. This data is comparable to 2017–2019 with regards to percentage of discarded amounts and total Medicare spending for discarded drugs each year, which ranged from approximately $700–750 million each year during that time. More than half of Medicare spending for discarded amounts in 2020 represents about 40 billing and payment codes (that is, HCPCS codes), for which 10 percent or more of the total charges for the drug were for discarded units. A large proportion of single source drugs with 10 percent or more discarded units are dosed based on patient's body weight or BSA. We note that the JW modifier data published on the CMS website is limited to only billing and payment codes that are published on the ASP Drug Pricing File.[94] There are likely additional billing and payment codes payable under Medicare Part B available in single-dose containers that would be subject to the JW modifier policy and are not reflected in the data discussed above.

When the calculated dose (based on weight or BSA) is drawn from one or more vials and any remaining amount of the drug is discarded. For example, if labeled dose of a drug is 20 mg/m^2, the dose for a patient with a BSA of 1.9 m^2 (the approximate average BSA of an adult male) would be 38 mg. If the drug is available in single-dose 60-mg vials, then 38 mg would be administered to the patient and 22 mg (36.67 percent) would be discarded. If the ASP payment limit amount (typically, ASP plus 6 percent) for this drug for a given quarter is $190 per 1 mg, the total payment for the amount of drug that was administered to the beneficiary would be $7,220 and for the amount of drug that was discarded would be $4,180. Both the amount of drug administered and the amount discarded (consistent with the discarded drug policy) are subject to the deductible and coinsurance. For a beneficiary who has already met the deductible, the coinsurance for the entire 60-mg vial would be $2280. Since the vial in this example contains enough drug to provide a 20 mg/m^2 dose to an individual with a BSA of 3 m^2, the full amount of drug labeled on the vial would be used in a small subset of patients.

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (hereinafter is referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. A refundable single-dose container or single-use package drug does not include a radiopharmaceutical or imaging agent, certain drugs requiring filtration, and certain new drugs. We are proposing implementation of section 90004 of the Infrastructure Act below including: how discarded amounts of drugs are determined; a definition of which drugs are subject to refunds (and exclusions); when and how often CMS will notify manufacturers of refunds; when and how often payment of refunds from manufacturers to CMS is required; refund calculation methodology (including applicable percentages); a dispute resolution process; and enforcement provisions.

We are proposing regulatory changes to implement new section 1847A(h) of the Act at 42 CFR part 414, subpart K.

2. Discarded Amounts

The JW modifier has existed since 2003, and since 2017 its use has been required on claims for separately payable Part B drugs that include discarded amounts of single use vials or

[88] *https://www.fda.gov/media/117883/download.*

[89] CF6603: *https://www.cms/gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf.*

[90] MLN Matters® Number MM9603: *https://www.cms/gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf.*

[91] *https://www.cms/gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.*

[92] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-PAQs.pdf.*

[93] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

[94] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

single use packages. Currently, there are no other modifiers to measure discarded units of Part B drugs. On the claim form, the amount of drug administered is billed on one line (reflected as billing units in the unit field); discarded amounts are billed on a separate line with the JW modifier (reflected as billing units in the unit field). The term ''billing unit'' is defined in section 1847A(b)(6)(B) of the Act as the identifiable quantity associated with a billing and payment code, as established by the Secretary. For example, in a circumstance where a single-dose container is labeled to contain 200 mg and the established billing unit for the billing and payment code is 2 mg, then there are 100 billing units in the vial. If 95 billing units (190 mg) are administered to the patient and 5 billing units (10 mg) are discarded, the 95 billing units are billed on one line, and the discarded 5 billing units are billed on another line using the JW modifier. Both line items are processed for payment.

The JW modifier must not be used to report discarded amounts of overfill, which is any amount of drug greater than the amount identified on FDA-approved labeling. Additional information on the overfill policy is available in the Physician Fee Schedule Final Rule published in the November 29, 2010 **Federal Register** (75 FR 73466 through 70). Contents of a vial or package that are considered overfill are not included in the total billing units contained in the vial or package and also do not count toward the number of billing units that are discarded.

Section 1847A(h) of the Act specifies that discarded amounts of refundable single-dose container or single-use package drugs are to be determined using a mechanism such as the JW modifier used as of the date of enactment of the Infrastructure Act or any successor modifier that includes such data as determined appropriate by the Secretary. For consistency with our current billing procedures and to minimize burden, we propose to use the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of a billing and payment code (that is, the identifiable quantity associated with a billing and payment code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, that were discarded for dates of service during such quarter. We propose to use the JW modifier (or any successor modifier that includes the same data) to identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act.

Currently, under the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System, hospital outpatient departments (HOPDs) and ASCs use the JW modifier to identify all separately payable drugs and biologicals for which there is an unused or discarded amount. For consistency with our current billing procedures we propose that HOPDs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes that are assigned status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) or status indicator ''G'' (Pass-Through Drugs and Biologicals) under the OPPS. Specifically, we propose that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, assigned status indicator ''K'' or ''G'' that were discarded for dates of service during such quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. Similarly, we propose that ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs described by HCPCS codes assigned payment indicator ''K2'' ('Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) under the ASC payment system. Specifically, we propose that ASCs would be required to report the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug (defined in the next section), if any, assigned status indicator ''K2'' that were discarded for dates of service during such quarter.

Consistent with section 1847A(h)(1)(C) of the Act, which excludes units that are packaged into the payment amount for an item or service and not separately payable, as well as current HOPD and ASC use of the JW modifier, we propose that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable, such as drugs for which payment is packaged under the OPPS or ASC payment system or drugs administered in the FQHC or RHC setting. Specifically, in HOPD setting and the ASC setting, the JW modifier does not apply to drugs that are described by HCPCS codes assigned status indicator ''N'' (Items and Services Packaged into APC Rates) under the OPPS or assigned to a payment indicator of ''N1'' (Packaged service/item; no separate payment made) under the ASC payment system.

Similarly, we propose to exclude from the refund amount those units of drugs for which payment is packaged into payment for a comprehensive ambulatory payment classification (C-APC) service under the OPPS. We propose to exclude such drugs when payment is packaged into a C-APC service which is assigned to an OPPS status indicator of ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC) or ''J2'' (Hospital Part B Services That May Be Paid Through a Comprehensive APC). For example, if a drug under the OPPS is assigned to status indicator ''K'', reports the JW or similar modifier, but is then packaged into a C-APC service assigned to a status indicator of ''J1'' or ''J2'', we would exclude from the refund those units associated with the packaged drug. For a complete list of all proposed OPPS status indicator and ASC payment indicator descriptors, please see the addendum D1 and addendum DD1 to the CY 2023 OPPS/ASC proposed rule, which we expect to issue at around the same time as this proposed rule.

As described in the section III.A.1 of this proposed rule (Background) and also in section III.A.6 of this proposed rule, section 1847A(h) of the Act requires manufacturers to provide refunds for discarded amounts of refundable single-dose container or single-use package drugs for which payment is made under Part B exceeding an applicable percentage of 10 percent of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter. Under our current discarded drug policy, no modifier is required when there are no discarded amounts from a single use vial or single use package drug. However, we are aware that the JW modifier is often omitted on claims, and it is unclear whether the absence of the JW modifier on a claim for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim. This

has led to incomplete data describing quantities of discarded amounts and the associated Medicare payments. There are a number of possible reasons why the modifier might be incorrectly omitted on the claim form, including provider burden for documentation or lack of awareness of the policy. In addition, there may not be strong incentive for appropriate JW modifier use because Medicare pays for administered and discarded amounts of the drug. For instance, if a provider administers a portion and discards a portion of a single-use vial, but bills for the entire vial as administered (incorrectly omitting the JW modifier), the provider payment and beneficiary coinsurance amounts would be the same as if the provider had correctly billed for the administered amounts and the discarded amounts (using the JW modifier). The JW modifier FAQs state that claims that do not use the modifier correctly may be subject to review, but we do not have quantifiable numbers regarding how often the modifier is omitted or how many discarded units are not accounted for because of such omissions. Because JW modifier data is incomplete and because refund amounts would rely on this data, we propose that for dates of service on or after January 1, 2023, the JW modifier be required on claims for all single-dose container or single use drugs for which any amount is discarded (as reflected in our current policy and proposed above), and a separate modifier be required on claims for these drugs when there are no discarded amounts. Specifically, we propose to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. To align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. So, on all claims for single use vials or single use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We believe the proposed JZ modifier requirement would not increase burden on the provider because under the current JW modifier policy, the provider already needs to determine whether or not there are any discarded units from a single use vial or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form.

We welcome comments on these proposals.

3. Refundable Single-Dose Container or Single-Use Package Drug

Section 90004 of the Infrastructure Act added section 1847A(h)(8) of the Act, which defines in subparagraph (A) of such section the term ''refundable single-dose container or single-use package drug'' as a single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act) or a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act) for which payment is made under Part B and that is furnished from a single-dose container or single-use package.

For the purposes of section 1847A(h) of the Act, we propose that the definition of ''refundable single-dose container or single-use package drug'' would apply to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a ''single-dose'' container or ''single-use'' package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a ''kit'' that is intended for a single dose or single use. As discussed above in the background, we note that the JW modifier data published on the CMS website is limited to only billing and payment codes that are published on the ASP Drug Pricing File. Therefore, there are likely billing and payment codes payable under Medicare Part B that would meet the proposed definition of refundable single-dose container or single-use package drug that are not found on the ASP drug pricing file or the JW modifier data published on the CMS website.

In our analysis of drugs that meet this definition, there may be a need to revise existing billing and payment codes or establish a new billing and payment codes for the purposes of implementing these provisions because estimated total number of units discarded and total allowed charges must be determined at the billing and payment code level for the purpose of calculating refund amounts (described below in section III.A.6. of this proposed rule). For example, if there is a drug that meets the definition of refundable single-dose container or single-use package drug that does not have a unique billing and payment code, a new code may be needed for the purposes of estimating the total number of units that were discarded during such quarter and the total allowed charges.

There may be drugs for which there are national drug codes (NDCs) of single-dose containers and NDCs of multiple-dose containers under the same FDA approval, and these NDCs are assigned to the same billing and payment code. We propose that for a drug to meet the definition of ''refundable single-dose container or single-use package drug,'' all NDCs assigned to the drug's billing and payment code must be single-dose containers or single-use packages, as described in each product's labeling.

Section 1847A(h)(8)(B) of the Act specifies that the term ''refundable single-dose container or single-use package drug'' excludes drugs that are either radiopharmaceuticals or imaging agents, drugs that require filtration during the drug preparation process, and drugs approved on or after the date of enactment of the Infrastructure Act (that is, November 15, 2021) for which payment under Part B has been made for fewer than 18 months. Our proposals for implementing this definition and its exclusions are discussed below.

a. Exclusions for Radiopharmaceuticals and Imaging Agents

Section 1847A(h)(8)(B)(i) of the Act excludes a drug or biological that is either a radiopharmaceutical or an imaging agent. We propose to identify radiopharmaceuticals (including therapeutic or diagnostic radiopharmaceuticals) and imaging agents (including contrast agents [95]) for purposes of the exception at section 1847A(h)(8)(B)(i) of the Act by language describing them as such in FDA-approved labeling.

We propose to codify the exclusion of radiopharmaceuticals and imaging agents from the definition of ''refundable single-dose container or single-use package drug'' at § 414.902.

b. Exclusions for Drugs Requiring Filtration

Section 1847A(h)(8)(B)(ii) of the Act excludes from the definition of refundable single-dose container or single-use package a drug approved by FDA for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. As the statute states, for the purposes of this exclusion, the filtration must occur prior to dilution and administration. Therefore, for example,

[95] *https://www.fda.gov/media/72295/download.*

the definition excludes those drugs requiring filtration in order to remove the product from a vial, such as drugs contained within ampules or certain liposomal products that require filtration when removing the product from the manufacturer's vial consistent with FDA labeling. However, drugs that require in-line filters only as part of the drug administration process would not meet this exclusion. We propose that, consistent with section 1847A(h)(8)(B)(ii) of the Act, requirement for filtration must be present on FDA labeling in order for the drug to be excluded.

Additionally, consistent with our longstanding interpretation of the distinction between multiple source drugs and single source drugs (see program instructions available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), we are proposing if there is any NDC under a single New Drug Application (NDA) or Biologics License Application (BLA) that requires filtration as described in section 1847A(h)(8)(B)(ii) of the Act, then all NDCs of such drug or biological (that is, any billing and payment code to which any such NDCs are assigned) would be excluded from the definition of refundable single-dose container or single-use package drug, even if other products under the relevant approval and assigned to that billing and payment code do not require such filtration. We believe this is appropriate because drugs and biologicals payable under Medicare Part B are billed at the level of the billing and payment code (not with the NDC of the individual product). If some products that require filtration and some products that do not require filtration are assigned to the same billing and payment code, we would not be able to distinguish (based on JW modifier data) which discarded amounts were from the filtered product and which were from the non-filtered product.

c. Exclusions for Drugs for Which Payment Under Medicare Part B Has Been Made for Fewer Than 18 Months

Section 1847A(h)(8)(B)(iii) of the Act excludes from the definition of refundable single-dose container or single-use package drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months. Typically, if their use is reasonable and necessary and all other coverage requirements are met, FDA-approved drugs become payable under Medicare Part B on the date which they are marketed in the United States. However, we are not able to reliably determine the exact date on which the first Part B claim was paid for a particular new drug because they are usually first billed using an unclassified drug or biological billing and payment code. Therefore, our ability to accurately determine when payment for a new drug has been made under Part B for 18 months is exceedingly limited. Because of the operational challenges with identifying the date of when the first Part B claim was paid for a new drug and because this exclusion would be operationally difficult to implement if the 18-month period ends in the middle of a calendar quarter, we believe it is appropriate to measure the 18-month period using the first day of the calendar quarter following the date of first sale as reported to CMS, which is a required field for reporting ASP data.[96] That is, for purposes of this exclusion, we propose to consider the 18-month period to begin on the first day of the calendar quarter following the date of first sale as reported to CMS for the drug. Because 18 months is the equivalent of six calendar quarters, under our proposed approach, refundable single-dose container or single-use package drugs approved or licensed by FDA on or after November 15, 2021 would be excluded from the definition of refundable single-dose container or single-use package, and thus, not subject to a refund, for the first 6 full calendar quarters following the date of first sale for any NDCs of such drug. Thereafter, that is, beginning with dates of service after the last day of the sixth full sales quarter, the drug would no longer be excluded from the definition of refundable single-dose container or single-use package drug. For example, if a drug that would otherwise meet the definition of refundable single-dose container or single-use package drug is approved by FDA in June 2023 and the first date of sale is June 20, 2023, the first day of the calendar quarter following the date of first sale for such drug would be sales occurring in the third calendar quarter of 2023 (July 1, 2023 through September 30, 2023), and we would consider the drug to be excluded from the definition for the next six quarters (that is, through December 31, 2024). As of January 1, 2025, the drug would no longer be excluded from the definition of refundable single-dose container or single-use package drug and would be subject to applicable refunds.

We propose that exclusion would apply only once for a drug. That is, it would apply for the first NDC of such drug assigned to a billing and payment code and paid under Medicare Part B. If additional NDCs in the same billing and payment code, such as a new vial size or ready-to-use syringe, were subsequently approved under the same FDA approved application (for example, under the same approved NDA or BLA number), marketed, and paid under Part B, these subsequent NDCs would not start a new 18-month exception period. We believe this proposed approach is appropriate to prevent a drug from periodic or continual exemption from reports and refunds due to new NDCs that are marketed under the same FDA-approval.

We propose to add a new definition at § 414.902 of ''refundable single-dose container or single-use package drug,'' which would be defined to mean a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information, except as otherwise specified. We welcome comment on the proposed implementation of these statutory exclusions.

4. Provision of Information to Manufacturers

Section 1847A(h)(1) of the Act requires the Secretary to provide each manufacturer of a refundable single-dose container or single-use package drug (as defined in section 1847A(h)(8) of the Act) with a report, for each calendar quarter beginning on or after January 1, 2023, that includes the following information:

- The total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The refund amount that the manufacturer is liable for pursuant to section 1847A(h)(3) of the Act.

We propose to use the definition of manufacturer at section 1847A(c)(6)(A) of the Act, which is codified at § 414.802 and defines manufacturer as any entity that is engaged in the following (this term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

[96] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.*

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

We propose to identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable single-dose container or single-use package drug. If such product does not have an NDC, we propose to use manufacturer information included on the ASP data submission for the product.

We propose that there be a lag between the date of service quarter and the date we send reports to manufacturers to allow for claims maturity from the date of service. To operationalize reports to manufacturers, we must consider the timing with regards to the availability of JW modifier data. Providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, so a lag exists between the date of service when a drug is administered and when the claim is submitted and adjudicated. Because of this lag in finalized claims, there may also be a lag in available JW modifier data for any given date of service quarter. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months, 99.83 and 100 percent of the claims, respectively, were considered to be final.

Section 1847A(h)(1) of the Act does not specify the interval by which reports for each calendar quarter must be sent to manufacturers. We propose that CMS provide an annual report to manufacturers with information for each calendar quarter. Sending reports (with information for each calendar quarter) annually would reduce the operational resources needed to implement this provision and would streamline the dispute resolution process as described in section III.A.7 of this proposed rule. We propose to send reports to manufacturers no later than October 1 of each year. We propose that the report reflect claims data that is finalized by the end of the second calendar quarter (that is, June 30) of the year in which the report is sent. This will allow time for CMS to analyze the data and calculate refund amounts (as discussed in section III.A.5 of this proposed rule) to provide reports to manufacturers no later than October 1. In addition, we propose that annual reports would include any additional lagged claims data not included for the quarters first reflected in the prior year's report.

In an effort to implement this provision in a timely manner, we propose to send the first report to manufacturers no later than October 1, 2023. Under our proposal, this first report would contain information only for the first calendar quarter of 2023, because that would be the only quarter for which we would have a substantial amount of claims data that is finalized by the end of the second calendar quarter of the year in which the report is sent. We propose to send the second annual report no later than October 1, 2024, and this report would include information for the second, third, and fourth quarters of 2023 and the first calendar quarter of 2024. It also would include any additional lagged claims for dates of service in the first calendar quarter of 2023 that were not included in the first report. Subsequent annual reports would be done in this manner, meaning that they would provide the information required under section 1847A(h)(1) of the Act for the last 3 quarters of the prior year, the first quarter of the current year, and lagged claims data not reflected for the last three quarters of the year that is two years prior and the first quarter of the prior year (that is, the quarters first reflected in the previous year's report). This means that reports (except for those in 2023 and 2024) would include information for eight calendar quarters: four new calendar quarters and four quarters with additional information for claims that were not yet finalized for those dates of service in the previous year's report. In this proposed approach, we would expect to capture JW modifier data and total allowed charges from over 99 percent of claims for dates of service in a given quarter. For example, the report sent to manufacturers in 2025 would include information for dates of service in the second, third, and fourth quarters of 2024 and the first quarter of 2025 plus additional lagged claims that were not included in the report sent in 2024 (that is, information for dates of service in the second, third, and fourth quarters of 2023 and the first quarter of 2024).

When lagged claims data is evaluated, any changes in the refund amount owed for those quarters and not already accounted for in the previous year's report would be calculated as described below in section III.A.6. of this proposed rule.

5. Manufacturer Provision of Refund

Section 1847A(h)(2) of the Act states that for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund for such quarter. As described in the previous section, we propose to issue reports for each calendar quarter on an annual basis. Section 1847A(h)(4) of the Act states that refunds under section 1847A(h)(2) of the Act must be paid in regular intervals as determined appropriate by the Secretary. We propose that refunds be paid in 12-month intervals (that is, annually) to align with our proposal to issue reports for each calendar quarter on an annual basis. Additionally, we believe requiring refunds to be paid on an annual basis is operationally optimal because it allows for some claims runout while administering reports in a timely manner following the date of service and leaves more time for dispute resolution (discussed below in section III.A.6. of this proposed rule), which we believe will be important for refund calculation accuracy. Including lagged claims data from the previous year's report allows more time for claims to be finalized for a given calendar quarter, subsequently represent a more accurate estimate of discarded units, and result in a more accurate refund calculation. Therefore, we propose to specify that the regular interval for the payment of refunds is annual and that refund amounts for the quarters reported in an annual report must be paid no later than December 31 of the year in which the report was sent to the manufacturer except in circumstances where a dispute is pending. In the case of a dispute, payment of the refund is due no later than 30 days after the resolution of the dispute. As discussed in more detail in the next section, we believe December 31 is an appropriate deadline because it would allow manufacturers to review their annual reports and initiate dispute resolution if needed. We propose to require manufacturers owing refunds to transmit payment in a form and manner specified by CMS.

We propose to reflect these provisions at § 414.940.

6. Refund Amount

Section 1847A(h)(3) of the Act provides, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after

January 1, 2023, that the refund for which the manufacturer is liable is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The payment limit amount for the refundable single-dose container or single-use package drug;

- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

Section 1847A(h)(3) of the Act specifies that the applicable percentage is 10 percent, but authorizes us to increase this percentage as appropriate, through notice and comment rulemaking, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act (discussed above in section III.A.3. of this proposed rule).

We propose to calculate the refund required under section 1847A(h)(1) of the Act using the number of discarded units for dates of services in the same calendar quarter to which the payment limit amount applies. We propose to estimate the total allowed charges during the quarter by multiplying the drug's payment limit amount for the quarter by the total number of units of the billing and payment code of such drug that were subject to JW modifier reporting (as described above in sections III.A.1. and 2. of this proposed rule) including those for which the JZ modifier would be required if no units were discarded. As specified in section 1847A(h)(1)(C) of the Act, the total number of units of the billing and payment code of a refundable single-dose container furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), exclude such units that are packaged into the payment amount for an item or service and are not separately payable.

To illustrate how the refund would be calculated, if 2,000 units of a billing and payment code for a given drug were unused and discarded during dates of service in the first calendar quarter of 2023, that number would be multiplied by the drug's payment limit amount for the first calendar quarter of 2023. If the payment limit amount was $100, that would be multiplied by 2,000 (the number of discarded units) to equal $200,000. If Medicare paid for 15,000 units of the billing and payment code subject to the JW modifier with dates of service in the first quarter of 2023, that would be multiplied by the same payment limit amount ($100) to determine the total allowed charges during the quarter ($1,500,000). Then, the applicable percentage (in this example, 10 percent) of those total allowed charges ($150,000) would be subtracted out to determine the refund amount. For the sake of this example, that would be $200,000 (the amount described in section 1847A(h)(3)(A)(i) of the Act) minus $150,000 (the amount described in section 1847A(h)(3)(A)(ii) of the Act) to equal a refund amount of $50,000 for the first calendar quarter of 2023.

Section 1847A(h)(3)(A) of the Act states that the refund amount is equal to an estimated amount and that the determination of amount that exceeds the applicable percentage of the estimated total allowed charges for a refundable single-dose container or single-use package drug during a given quarter. Exact amounts are likely not attainable for these numbers because of, for example, lagged claims data, appeals, or reversals in the case of an audit. To obtain the most accurate estimates possible, we propose above in section III.A.2 to provide information and determine any refund amount for discarded refundable single-dose container or single-use package drugs annually, and to include additional lagged claims data not included in the previous year's report. Based on claims maturity data, we expect this approach would capture over 99 percent of claims for a given date of service quarter in an effort to make the most accurate estimates possible for the purposes of calculating refund amounts. If the assessment of lagged claims data increases the refund amount for a quarter, the manufacturer would be liable for that additional refund amount, which would be reflected in the report. If the assessment of lagged claims data decreases the refund amount for a quarter, we propose that any overpayment be corrected. In the event that an assessment of lagged claims data for a calendar quarter causes the product of total discarded units and the payment limit amount to fall below the applicable percentage, which would result in no refund due from that manufacturer for the given quarter, we propose that any overpayment be corrected. We solicit comments on the operational process of overpayment correction.

We propose to reflect these provisions at § 414.940.

a. Increased Applicable Percentage for Drugs With Unique Circumstances

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary.

At this time, we do not propose an increase of the applicable percentage for any drugs with unique circumstances. We expect that for most drugs supplied in single-dose containers, the amount of drug indicated on the vial or container reflects the amount of drug that could potentially be administered to a patient. This is consistent with FDA regulations at 21 CFR 201.51(g), which provide that for drugs in ampules or vials intended for injection, the declaration of net quantity of contents on the label is considered to express the minimum quantity of contents and that variation above the stated measure must comply with the excess volumes set forth in the United States Pharmacopeia (USP). FDA guidance for industry [97] explains that USP General Chapter 1151 *Pharmaceutical Dosage Forms* provides excess volume recommendations for mobile and viscous liquids in a range of fill volumes, noting that the excess volumes recommended are usually sufficient to permit withdrawal and administration of the labeled volumes. In this guidance, FDA recommends that single-dose vials should not contain a significant volume beyond what would be considered a usual or maximum dose for the expected use of the drug product.

We recognize there may be very rare cases in which, as part of a drug's FDA-approved preparation and administration in labeling, the amount of drug identified on the package or labeling far exceeds the amount administered to a patient, thus leading to a substantial percentage of drug that is discarded. For example, in the case of a drug that is reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, there is substantial amount of reconstituted hydrogel that adheres to

[97] *https://www.fda.gov/media/88138/download.*

the vial wall during preparation.[98] In this instance, the drug adhering to the vial wall (and not able to be extracted from the vial) must be discarded, which leads to a higher percentage of discarded units billed with the JW modifier. If the labeled amount of the package is 80 mg and the maximum extracted amount from the vial guarantees delivery of the maximum dose of 60 mg, then there would be at least 25 percent discarded units. In the case that a patient does not require the maximum dose, the percent of discarded units would be even higher. In this circumstance, an applicable percentage of 35 percent may be appropriate because it would allow for the amount drug diluted in hydrogel that adheres to the vial wall (25 percent) plus an additional 10 percent to align with the applicable percentage for drugs without a unique circumstance.

We are considering whether we should adopt a higher applicable percentage for a drug in this circumstance. We welcome comments on specifying a higher applicable percentage for drugs that are diluted in hydrogel and administered via the pyelocaliceal route, and we welcome comments on whether an applicable percentage of 35 percent would be appropriate in this circumstance. We welcome comments on whether there are other drugs with unique circumstances as described under section 1847A(h)(3)(B)(ii) of the Act that may warrant an increase in the applicable percentage.

7. Dispute Resolution

As a part of implementing this provision, we recognize the need for establishing a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. Although a dispute resolution process is not expressly required by section 1847A(h) of the Act, we believe that proactively establishing such a process will aid in the successful implementation of this provision. We propose that each manufacturer have an opportunity to dispute the report by submitting an error report as described in this section.

We propose that to assert that there have been one or more errors in a report, a manufacturer must submit a dispute with each asserted error. We propose that the dispute must include the following information: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

We propose that in order to dispute a report, manufacturers must assert any basis for contesting its refund calculation during the 30-day period following the issuance of the report. We would evaluate error reports and would decide whether the information (such as number of discarded billing units or refund amount calculation) requires correction based on the information provided. We propose that we would provide manufacturers who have submitted a dispute a response to each dispute and inform manufacturers of the final refund amount no later than 30 days after receipt of the dispute. We propose that if we find that a different refund amount is owed than what was stated on the report, we would issue a new report with updated discarded amounts and/or refund. We propose that if we disagree with the dispute, we would notify the manufacturer that refund amount on the report is still owed and should be paid as described above in section 5 (no later than December 31 of the year in which the report was sent). We welcome comment on whether CMS should develop an appeal mechanism, which we will consider for future rulemaking.

We propose to codify the dispute resolution process at § 414.940.

8. Enforcement

a. Audits

Section 1847A(h)(6)(A)(i) of the Act requires that we perform periodic audits on each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under section 1847A(h) of the Act with respect to such drug and such refunds. We propose to specify at 414.940(e) that we periodically audit manufacturers of refundable single-dose container or single-use package drugs consistent with this requirement. We welcome comments about what such audits should entail, which we will consider for future rulemaking.

Section 1847A(h)(6)(A)(ii) of the Act requires us to conduct periodic audits of claims submitted under Medicare Part B with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) of the Act. Under the JW modifier policy, claims for drugs furnished on or after January 1, 2017 containing billing for discarded drugs that do not use the JW modifier may be subject to review.[99] We propose that our review contractors would periodically review Part B medication claims to ensure the JW modifier, JZ modifier (if adopted), and discarded drug amounts are billed appropriately consistent with our normal claims audit policies and protocols.

b. Civil Money Penalty

Provisions in section 1847A(h)(6)(B) of the Act give the Secretary authority to impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who fails to comply with the requirement under section 1847A(h)(2) of the Act for such drug for a calendar quarter.

As set forth in section 1847A(h)(6)(B) of the Act, the civil money penalty would be an amount equal to the sum of—

- The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and
- 25 percent of such amount.

We propose to codify the civil money penalty at § 414.940.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home

[98] *https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3d3d5053-5427-4a68-a40b-edb60699521e.*

[99] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to new payment limits on the AIR, and this limit will be determined for each RHC in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

b. Care Management Services in RHCs and FQHCs

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to separately recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

A separate payment was established in the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088) for RHCs and FQHCs that furnish Chronic Care Management (CCM) services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule with comment period (82 FR 53169 and 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018.

HCPCS code G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month.

In the CY 2019 PFS final rule (83 FR 59683), we explained for CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised G0511 were CPT 99490 (20 minutes or more of CCM services), CPT 99487 (60 minutes or more of complex CCM services), and CPT 99484 (20 minutes or more of BHI services).

We also explained that another CCM code was introduced for practitioners billing under the PFS, 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487 (83 FR 56983). Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2020 PFS final rule with comment (84 FR 62692), we established a separate payment for Principle Care Management (PCM) services under the PFS. PCM services include comprehensive care services for a single high-risk disease or complex condition, typically expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065. HCPCS code G2064 is for at least 30 minutes of PCM services furnished by physicians or nonphysicians during a calendar month. HCPCS code G2065 is for at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or non-physician during a calendar month.

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that since the requirements for the new PCM codes were similar to the requirements for the services described by HCPCS code G0511, we added HCPCS code G2064 and G2065 to G0511 as a general care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS G2064 and G2065). Finally, we note that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the current payment rate for HCPCS G0511 is the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487,

99484, and 99491), and PCM codes (CPT codes 99424 and 99425).

Additional information on care management requirements is available on the CMS Care Management Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html* and on the CMS RHC and FQHC Web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

2. New Care Management Codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)

Consistent with the discussion earlier in section II.E.4 of this proposed rule, there are two new HCPCS codes proposed to describe CPM and the proposed CPM codes would be created to separately pay for a specified set of pain management and treatment services, specifically including the administration of validates rating scales, and a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes.

(1) HCPCS codes GYYY1: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, *e.g.,* physical therapy and occupational therapy, and community-based care, as appropriate. Required face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.) and (2) HCPCS code GYYY2: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month). For GYYY1, CPM services, we are requiring an face-to-face visit of at least 30 minutes provided by a physician or other qualified health professional, per calendar month to a beneficiary who has a diagnosis of pain that has lasted more than 3 months, which could be the result of an underlying medical disease or condition. HCPCS code GYYY2 will apply to up to three units of an additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (listed separately in addition to GYYY1). The new codes for CPM would be valued using crosswalks to the CY 2023 ratesetting inputs for the PCM services, CPT codes 99424 and 99425.

The new coding and payment for general BHI services, as described in section II.E.4 of this proposed rule, would be a new HCPCS code (GBHI1): *(Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with an/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team)* describing general BHI services performed by clinical psychologists (CPs) and clinical social workers (CSWs). The payment rate for the new General BHI code would be based on the payment rate for the current general BHI code, 99484. CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs (§ 405.2411(a)(6)).

The requirements for the proposed CPM service (that is, HCPCS code GYYY1) are similar to the requirements for the general care management services furnished by RHCs and FQHCs and as such, we believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. The pain management coordination included in services, such as office visits, do not always adequately describe the non-face-to-face pain management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated pain care management described in the HCPCS code, such as the assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care.

Allowing separate payment for CPM services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. We are not proposing to utilize the add-on HCPCS code GYYY2 for RHC/FQHC payments because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners, as is the case for practitioners under the PFS. In an effort to be consistent with the new services that are being proposed for practitioners billing under the PFS, we are proposing to include CPM services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code GYYY1 would be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, we propose no change to the average used to calculate the G0511 payment rate.

In addition, since CPs and CSWs are considered practitioners that can provide services in RHCs/FQHCs, in this proposed rule we clarify that when CPs and CSWs provide the services described in HCPCS code GBHI1 in an RHC or FQHC, they can bill HCPCS code G0511.

If finalized as proposed, RHCs and FQHCs that furnish the new CPM and GBHI services performed by CPs and CSWs would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023. The payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC and FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) and PCM codes (CPT codes 99424 and 99425) and would be updated annually based on the PFS amounts for these codes.

In future rulemaking, we may consider other approaches for

calculating the rate of HCPCS code G0511 as the number of services is growing each year. For example, we could value HCPCS code G0511 using a weighted average of the services that comprise HCPCS code G0511 or using the national average of the top three services comprising HCPCS code G0511. We welcome comments on potential methodologies.

3. Conforming Technical Changes to 42 CFR 405.2463

Last year in the CY 2022 PFS final rule with comment (86 FR 65211), we finalized a policy to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. This change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, we finalized a revision to the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

We also finalized a revision to the regulation under § 405.2469, FQHC supplemental payments, to state that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. At § 405.2469, we also finalized a revision to paragraph (d) to describe the same in-person visit requirement referenced in § 405.2463.

The Consolidated Appropriations Act, 2022 (Pub. L. 117–103) (CAA, 2022) was signed into law on March 15, 2022, and included extension of a number of Medicare telehealth flexibilities established during the PHE for a limited 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. Specifically, section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE. Payment would continue to be made under the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

We do not believe it necessary to conform the regulation to this temporary provision. However, another provision applicable to RHCs and FQHCs requires conforming regulatory text changes. Section 304 of the CAA, 2022 delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology which requires conforming regulatory text changes. For RHCs and FQHCs, in-person visits will not be required until the 152nd day after the end of the PHE for COVID–19. We note that while the extensions of mental health telehealth visits under section 304 of the CAA, 2022 were placed into paragraphs of section 1834 of the Act applicable only to hospice patients served by RHCs and FQHCs, the overall intent of the amendments made by section 304 of the CAA, 2022 appear to be to provide an exception to the limitations otherwise in place on payment for mental health visits that are not in-person visits. Therefore, we are proposing to apply the 151-day extension of non-in-person visits to all RHC and FQHC mental health visits.

Therefore, we are proposing to make conforming regulatory text changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we propose to amend paragraph (b)(3) and at § 405.2469 ''FQHC supplemental payments'' we proposed to amend paragraph (d) to include the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19.

In addition, several other provisions of the CAA, 2022 would apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs.

Section 301 of the CAA, 2022 amended section 1834(m)(4)(C) of the Act to add a new clause (iii) expand the originating site requirements to include any site in the U.S. at which the beneficiary is located, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID–19. It also prohibits an originating site facility fee from being paid unless the site is a setting included on the originating site list in section 1834(m)(4)(C)(ii) of the Act, excluding the home of an individual.

Section 305 of division P, title III, subtitle A of the CAA, 2022 amended section 1834(m) to extend coverage and payment of telehealth services that are furnished via audio-only telecommunications system for the 151-day period beginning on the first day after the end of the PHE for COVID–19.

Section 309 of division P, title III, subtitle A of the CAA, 2022 authorized the Secretary to implement the Medicare telehealth provisions via program instruction or otherwise. Therefore, given that the end date of the PHE is not yet known and may occur prior to the provisions of this rule being finalized, we note that we intend to issue program instruction or other subregulatory guidance to implement the provisions of this section of this rule to ensure a smooth transition after the declared end of the PHE for COVID–19.

4. Specified Provider-Based RHC Payment-Limit Per-Visit

a. Background

Beginning April 1, 2021, provider-based RHCs that meet qualifications in section 1833(f)(3)(B) of the Act are entitled to the special payment rules

described in section 1833(f)(3)(A) of the Act. In order to have their payment limit established based on their applicable All-Inclusive Rate (AIR) and remain this way instead of being based on the national statutory payment limit as applicable in section 1833(f)(2) of the Act, RHCs must meet the following specified criteria:

- As of December 31, 2020, the provider-based RHC was in a hospital with less than 50 beds and after December 31, 2020 in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the PHE for COVID–19); and one of the following circumstances:

++ As of December 31, 2020, was enrolled in Medicare (including temporary enrollment during the PHE for COVID–19); or

++ Submitted an application for enrollment in Medicare (or a request for temporary enrollment during the PHE for COVID–19) that was received not later than December 31, 2020.

In accordance with section 1833(f)(3)(A)(i)(I) of the Act, beginning April 1, 2021, for provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or (2) the national statutory payment limit for RHCs per visit. We note, the MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264) and the proposal to rebase and revise the MEI for CY 2023 can be found in section II.N. of this proposed rule.

In a subsequent year (that is, after 2021), the provider-based RHC's payment limit per visit shall be set at an amount equal to the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs.

In accordance with section 1833(f)(3)(A)(i)(II) of the Act, beginning April 1, 2021, for provider-based RHCs that meet the specified criteria under section 1833(f)(3)(B) of the Act, but did not have a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be at an amount equal to the greater of: (1) the per visit payment amount applicable to the provider-based RHC for services furnished in 2021; or (2) the national statutory payment limit for RHCs.

In a subsequent year (that is, after 2022), the provider-based RHCs payment limit per visit will be the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs.

Once a provider-based RHC meets the qualifications of section 1833(f)(3)(B) of the Act, it will lose its designation if the hospital does not continue to have less than 50 beds, beyond the exemptions provided for the COVID-19 PHE. If this occurs the provider-based RHC would be subject to the statutory payment limit per visit applicable for such year and will not be able to regain the specified provider-based payment limit.

In the CY 2022 PFS final rule (86 FR 65204), we discussed the provisions in section 1833(f) of the Act [100] and finalized conforming regulations under § 405.2462. On March 16, 2021, we issued Change Request 12185, Transmittal 10679, to instruct the Medicare Administrative Contractors (MACs) to establish the provider-based RHC payment limits per visit in accordance with section 1833(f)(3)(A), beginning April 1, 2021. Change Request 12185, Transmittal 10679, was rescinded and replaced by Transmittal 10780 issued on May 4, 2021.[101] Change Request 12489, Transmittal 11130, issued on November 19, 2021, implemented the RHC payment limits for CY 2022.[102]

b. Clarification to the RHC Payment Limit for Specified Provider-Based RHCs

As we state above, section 1833(f)(3)(A) of the Act instructed CMS to set payment limits per visit for specified provider-based RHCs under certain payment rules. For specified provider-based RHCs that had a per visit payment amount (that is, an AIR) established for services furnished in 2020, beginning April 1, 2021, section 1833(f)(3)(A)(i)(I) of the Act requires the payment limit per visit to be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 or; (2) the statutory payment limit per visit as described in section 1833(f)(2)(A) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, the payment limit per visit shall be set at an amount equal to the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in the MEI or; (2) the statutory payment limit described in section 1833(f)(2) of the Act as applicable.

For specified provider-based RHCs that *did not* have an AIR established for services furnished in 2020, beginning April 1, 2021, section 1833(f)(3)(A)(i)(II) of the Act requires the payment limit per visit shall be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2021 or; (2) the statutory payment limit per visit as described in section 1833(f)(2)(A) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, the payment limit per visit shall be set at an amount equal to the greater of: (1) the amount established in the previous year increased by the percentage increase in the MEI or; (2) the statutory payment limit described in section 1833(f)(2) of the Act as applicable.

In the CY 2022 PFS final rule (86 FR 65201), we interpreted the ''per visit payment amount'' to align with the interim rate process the MACs use in determining an RHC's AIR.[103] That is, as explained in § 405.2464(a) the AIR is determined by the MAC using the most recently available cost report. Therefore, using the RHCs discussed in section 1833(f)(3)(A)(i)(I) of the Act as an example, we interpreted the term ''services furnished in 2020'' to mean the period at which the services were furnished in 2020 and that costs for those services were reported. We acknowledged that there may be more than one cost report that reports costs for services furnished in calendar year 2020 and explained that since section 1833(f)(3)(A)(i)(I)(aa) of the Act requires the ''per visit payment amount'' to be increased by the CY 2021 MEI, if a provider has a cost reporting period that differs from a calendar year time-period

[100] As amended by Division CC, section 130 of the Consolidated Appropriations Act of 2021 (P.L. 116–260), December 27, 2020). Section 2 of H.R. 1868 (Pub. L. 117–7), enacted April 14, 2021, provided a technical correction to section 1833(f) of the Act. The amendments made by this technical correction took effect as if included in the enactment of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260).

[101] *https://www.cms.gov/files/document/r10780OTN.pdf.*

[102] *https://www.cms.gov/files/document/r11130cp.pdf.*

[103] Note: A discussion of the interim rate process is provided in section III.A.2 of the CY 2022 PFS final rule (86 FR 65198 and 65199).

(that is, January 1, 2020 through December 31, 2020) then the MACs should use data based on the relevant cost report period ending in 2020.

In the CY 2022 PFS final rule (86 FR 65200), we received comments from interested parties expressing concern about how the payment limit per visit is established for specified provider-based RHCs. To be appropriately reflective of an individual clinic's true costs, one commenter stated that grandfathered, clinic specific, upper payment limits should be based on the final cost settled amount for cost reporting periods that end in 2020, or 2021 (for grandfathered RHCs that did not have cost reporting period that end in 2020), not an interim rate. If an interim final rate is necessary for the time period before final cost settled rates are adjudicated, the commenter suggested that CMS set interim clinic-specific upper limits only until such time that a final rate is established. In our response to these comments, we agreed, and stated that what the commenter described was aligned with the statute and how we implemented the payment limit per visit for specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, had their payment limit per visit based on their AIR determined from their final settled cost report ending in 2020 increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 (CY 2021 MEI of 1.4 percent). However, if the product of those two numbers (AIR established for services furnished in 2020 * 1.014) were less than the national statutory payment limit of $100, their payment limit per visit was established at $100. With regard to a specified provider based RHC that did not have an AIR established for services furnished in 2020 and received an interim rate until the MAC accepted and finalized the RHC's initial cost report, we again agreed with the commenter. We believed that what the commenter described also aligned with the statute and how we implemented the payment limit per visit for these specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that did not have an AIR established for services furnished in 2020, would have their payment limit per visit established based on their AIR determined by MACs using the RHC's final settled cost report ending in 2021. The interim rate estimate would be reconciled at cost report settlement for the cost reporting period ending in 2021 which is used to establish the RHC's payment limit per visit for services furnished in 2021.

Since publication of the CY 2022 PFS final rule, interested parties requested clarification regarding the timing of cost reports, specifically if the payment limit could be set using a short cost report (less than 12 consecutive months). In the CY 2022 PFS final rule (86 FR 65198 through 65202), we did not specifically address requiring the cost report to span a full 12-consecutive month period or whether MACs, following their interim rate setting process, could establish the payment limit using a specified RHC's short period cost report (less than 12-consecutive months). Since many questions were raised subsequent to the publication of the CY 2022 PFS final rule regarding the use of short-period cost reports (less than 12 consecutive months) versus 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs, in this proposed rule, we are providing a discussion of this issue and providing clarification.

For purposes of establishing the payment limit effective April 1, 2021 for specified provider-based RHCs defined in section 1833(f)(3)(A)(i)(I) of the Act, that is, had an AIR established for services furnished in 2020, we are proposing that MACs use the cost report ending in 2020 that reports costs for 12 consecutive months. If the RHC does not have a 12 consecutive month cost report ending in 2020, the MACs should use the next most-recent final settled cost report that reports cost for 12 consecutive months. This proposal would impact specified provider-based RHC's that had an established AIR for services furnished in 2020 but submitted a short cost report (less than 12 consecutive months) ending in 2020 since that period would have been used by MACs for determining the RHC's payment limit per Change Request 12185, Transmittal 10679.

The payment limit per visit is based on each specified provider-based RHC's AIR determined from their final settled cost report ending in 2020 when such cost reporting period is for 12-consecutive months. If a 12-consecutive month cost report ending in 2020 is not available, the MAC should use the next available 12-consecutive month cost report that reports costs for RHC services furnished in 2020, (for example, a cost reporting period October 1, 2020 through September 30, 2021 would be acceptable).

We considered the idea of combining cost report data that spans from the end of one year into the next year to equal a 12-consecutive month cost report (for example, a cost report that consists of three months ending December 31, 2020 plus a cost report that ends July 31, 2021) and prorating the rates from the time services were furnished in both years. We decided against combining cost report data to equal a 12-consecutive month cost report because prorating may result in an inaccurate AIR. We seek comment on whether we should combine cost report data that spans from one year into the next year to equal a 12-consecutive month cost report.

Consequently, for purposes of establishing the payment limit effective April 1, 2021 for specified provider-based RHCs defined in section 1833(f)(3)(A)(i)(II) of the Act (that is, those that did not have an AIR established for services furnished in 2020), we are proposing that MACs use the cost report ending in 2021 that reports costs for 12 consecutive months. If the RHC does not have a 12-consecutive month cost report ending in 2021, the MACs should use the next most-recent final settled cost report that reports cost for 12 consecutive months.

In addition, for those specified provider-based RHCs who did not have an AIR established for services furnished in 2020 the 2021 MEI percentage increase update would not be applied. As discussed in the CY 2022 PFS final rule (86 FR 65200), for those specified provider-based RHCs, the payment limit per visit would be at an amount equal to the greater of: (1) The per visit payment amount applicable to the provider-based RHC for services furnished in 2021; or (2) the national statutory payment limit for RHCs, and since the MEI is already built in the rate for services furnished in 2021 adding an MEI update would be duplicative. Therefore, those specified provider-based RHCs that did not have an AIR established for services furnished in 2020 would receive the CY 2023 percentage increase in the MEI, which will be based on the proposed 2017-based MEI update. We note that in section II. M. of this proposed rule, we are proposing to rebase and revise the MEI from a 2006-base year to a 2017-base year.

We believe 12 consecutive months of cost report data will more accurately reflect the costs of providing RHC services and will establish a more accurate base from which the payment limits will be updated going forward.

We seek comment on this proposed interpretation.

C. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016 through June 30, 2016. The first data reporting period occurred from January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties (CMPs) for failure to report applicable information with respect to the initial data reporting period.[104]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage (MA) plan payments under Part C from the denominator of the Medicare revenues threshold calculation, in an effort to broaden the types of laboratories qualifying as an applicable laboratory. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period. Because MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount than what they would have been compared to if MA plan payments remained in the denominator. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019 through June 30, 2019, and the next data reporting period was scheduled to take place from January 1, 2020 through March 31, 2020, with the next update to the Medicare payment rates for these tests based on that reported applicable information scheduled to take effect as of January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502.

Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

[104] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website.[105]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted on December 20, 2019), and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116-136, enacted on March 27, 2020), made revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs under section 1834A of the Act. Additionally, the CARES Act made revisions to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 105(a)(1) of the FCAA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2021 through March 31, 2021; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period of January 1, 2021 through March 30, 2021 would be the period of January 1, 2019 through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the CARES Act further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022 through March 31, 2022. As amended by the CARES Act, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that: (i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2021; (ii) reporting is required during the period beginning January 1, 2022, and ending March 31, 2022; and (iii) reporting is required every 3 years after the period described in clause (ii).

The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2022 through March 31, 2022) would have been based on the data collection period of January 1, 2019 through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2022 through 2024, instead of CYs 2021 through 2023.

In the CY 2021 PFS rulemaking (85 FR 50210 through 50211 and 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we finalized revisions to § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019. We also revised § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, enacted on December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023 through March 31, 2023; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023 through March 31, 2023) will continue to be based on the data collection period of January 1, 2019 through June 30, 2019, as defined in § 414.502.

[105] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

Section 4 of PMAFSCA further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

5. Proposed Conforming Regulatory Changes

In accordance with section 4(b) of PMAFSCA, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise § 414.502 to update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2023. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4(b) of PMAFSCA. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2022 and 2023 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016 through June 30, 2016. Under current law, the CLFS payment rates for CY 2024 through CY 2026 will be based on applicable information collected during the data collection period of January 1, 2019 through June 30, 2019 and reported to CMS during the data reporting period of January 1, 2023 through March 31, 2023.

6. Laboratory Specimen Collection Fee and Travel Allowance Proposals

In general, section 1833(h)(3) of the Act requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), in addition to the amounts provided under the Medicare CLFS. In this section of the proposed rule, we are proposing to codify our longstanding specimen collection fee policies at § 414.523(a)(1) and our travel allowance policies at § 414.523(a)(2), as well as proposing certain changes to modify or clarify those policies.

a. Background on Laboratory Specimen Collection Fee Policy

Medicare Part B, which includes a variety of outpatient services, generally covers medically necessary CDLTs when a doctor or non-physician practitioner orders them. Medically necessary CDLTs are generally not subject to coinsurance or deductible. Section 1833(h)(3)(A) of the Act provides that, in addition to the amounts provided under fee schedules (for tests furnished before January 1, 2017) or under section 1834A of the Act (for tests furnished on or after January 1, 2017), the Secretary shall provide for and establish a nominal fee to cover the appropriate costs in collecting the sample on which a CDLTs was performed and for which payment is made under Medicare Part B, except that not more than one such fee may be provided with respect to samples collected in the same encounter. As detailed later in this section of the proposed rule, we provided manual instructions regarding payment of the nominal specimen collection fee in the Medicare Claims Processing Manual Pub. 100–04, chapter 16, section 60.1,[106] but we have not reflected these general policies in our regulations.[107] The HCPCS codes for the nominal specimen collection fees currently listed on the CLFS (HCPCS codes 36415, P9612, and P9615 [108]) have a payment rate of $3. Neither the annual deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection fees or travel allowance for laboratory tests.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1834A(b)(5) to the Act, which increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a specimen collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a HHA. Therefore, effective April 1, 2014, the nominal fee that would otherwise apply for a specimen collected from an individual in a SNF or by a laboratory on behalf of a HHA is $5, and the relevant HCPCS code is G0471.[109] We implemented this provision in our regulations at § 414.507(f). However, as we discuss below, we are proposing to codify our specimen collection fee policies in § 414.523(a)(1), including moving that provision from § 414.507(f) to § 414.523(a)(1)(iv).

In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), which appeared in the **Federal Register** on April 6, 2020 (85 FR 19230), we established that Medicare would pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 CDLTs for homebound and non-hospital inpatients (85 FR 19256 through 19258). Under this policy, the nominal specimen collection fee for COVID–19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a SNF and individuals whose samples are collected by laboratory on behalf of an HHA is $25.46. We indicated in that IFC that this specimen collection fee policy was established for the duration of the PHE for COVID–19 (85 FR 19256) and noted in that IFC and subsequent rules (86 FR 39309; 86 FR 65327) that this policy will end once the PHE for the COVID–19 pandemic has ended.

In the CY 2022 PFS proposed rule (86 FR 39310), we requested broad

[106] The Medicare Claims Processing Manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912*.

[107] In 1993, we proposed to implement the payment methodologies for the specimen collection fee and travel allowance in the regulations, see 53 FR 43837 through 43838, but did not finalize those proposals.

[108] HCPCS codes and long descriptors: 36415 (Insertion of needle into vein for collection of blood sample); P9612 (Catheterization for collection of specimen, single patient, all places of); P9615 (Catheterization for collection of specimen(s) (multiple patients)).

[109] HCPCS code and descriptor: G0471 (Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a labortory on behalf of a home health agency (HHA)).

comments on our policies for specimen collection fees for consideration for possible updates to those policies in the future through notice and comment rulemaking. We requested comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), how specimen collection practices may have changed as a result of, or from insight gained during, the PHE for COVID–19, and what additional resources might be needed for specimen collection for COVID–19 CDLTs and other tests after the PHE ends, as well as comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients. In the CY 2022 PFS final rule (86 FR 65327 through 65328), we described the comments received and provided responses to those comments. We expressed appreciation for the comments regarding the nominal specimen collection fees for the collection of specimens for COVID–19 CDLTs and acknowledged that the types of resources utilized and supplies needed for specimen collection have been influenced by the PHE for COVID–19. We stated that although we would not extend the increased payment amount beyond the PHE, we would take the feedback received from the comment solicitation into consideration for possible future rulemaking and guidance.

b. Longstanding Laboratory Specimen Collection Fee Policies and Practices

We have longstanding policies and practices regarding the statutory requirements under section 1833(h)(3)(A) of the Act for the laboratory specimen collection fee, which are currently described in the Medicare Claims Processing Manual Pub. 100-04, chapter 16, § 60.1. However, we do not have corresponding regulations text related to the manual guidance and some of the manual guidance is no longer applicable. The manual guidance specifies when a specimen fee is allowed and not allowed. In particular, the manual provides guidance on the following topics: (1) specimen drawing by a physician; (2) specimen drawing by an independent laboratory; (3) specimen drawing for a dialysis patient; and (4) the coding requirements for specimen collection. We note that laboratory services, including specimen collection and travel for specimen collection, paid under the CLFS must be reasonable and necessary as required under section 1862(a)(1)(A) of the Act.

Specifically, the guidance provides that a specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (that is, inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for a throat culture or a routine capillary puncture for clotting or bleeding time. Additionally, the specimen fee will not be paid to anyone who has not extracted the specimen. The manual guidance addresses the number of specimen collection fees allowed for each specimen type per patient encounter. The manual also addresses how to treat a series of specimens; when a series of specimens is required to perform a single test (for example, a glucose tolerance test), the series is treated as a single encounter.

The Medicare Claims Processing Manual (chapter 16, § 60.1.1) describes specimen collection fees for physicians. Specifically, the manual states that Medicare allows a specimen collection fee for physicians only when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.

In reviewing the specimen collection criteria for physicians to be paid for this service, we had concerns regarding outdated terminology and the eligibility criteria for these suppliers to bill Medicare for a specimen collection fee. For example, we found that these criteria were established prior to January 1, 1992, which is when Medicare began to pay for physicians' services under section 1848 of the Act (56 FR 59502). Since that time, the provision of laboratory services and physicians' services have evolved. Therefore, we evaluated those criteria as they would apply today. In consideration of current standards of practice, we analyzed utilization of the specimen collection Current Procedural Terminology (CPT®) codes to determine if the physician office setting is billing for this fee. We found that, in 2019, office-based physician and nonphysician practitioners had 67.4 million claims billed with specimen collection, comprising 31.1 percent of all specimen collection claims.

We also looked to the PFS to see if there are similar services that physicians and nonphysician practitioners can bill and be paid for under section 1848 of the Act. We found that there are codes available that address collection of blood, for example, CPT® codes 36410 (Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture)). These findings confirm specimen collection occurs in the physician's office setting and there are coding options to bill for that service via the PFS when applicable. Therefore, we believe the criteria currently included in the manual for physician eligibility for the CLFS specimen collection fee no longer apply. We would not reflect those policies in regulation and would remove this section of the manual accordingly.

The Medicare Claims Processing Manual (chapter 16, § 60.1.2) describes policies for specimen drawing by independent laboratories. Specifically, the manual states the following:

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another. Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. Payment for the specimen collection fee is made based on the CLFS. The technician must personally draw the specimen, for example, venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is: (1) not confined to the facility; or (2) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, for example, urine or sputum, a specimen pickup service would not be considered medically necessary. The manual then refers to the Medicare Benefit Policy Manual, Chapters 7 and 15 of Pub. 100–02, for a discussion of ''homebound'' and a more complete definition of a medically necessary laboratory service

to a homebound or an institutional patient.

Under sections 1814(a) and 1835(a) of the Act, an individual shall be considered to be ''homebound'' or ''confined to his home'' if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered ''confined to his home,'' the condition of the individual should be such that there exists an inability to leave home such that leaving home requires a considerable and taxing effort by the individual. Moreover, § 424.22(a)(1)(ii) describes homebound for the purposes of the provision of Medicare home health services as home health services are or were required because the individual is or was confined to the home, as defined in sections 1835(a) and 1814(a) of the Act, except when receiving outpatient services. Additionally, chapter 15 of the Medicare Benefit Policy Manual [110] Section 60.4.1—''Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit'' describes the definition of homebound in that the patient is confined to his/her home, which has two criteria: (1) the patient must either, because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence; or (2) otherwise have a condition such that leaving his or her home is medically contraindicated. The patient must also meet two additional requirements defined in criterion two such that there must exist an inability to leave home; and leaving home must require a considerable and taxing effort.

The Medicare Claims Processing Manual (chapter 16, § 60.1.2) also explains the information that must be included on an independent laboratory claim for specimen drawing. Specifically, the manual states that in addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing ordered by a physician should be appropriately annotated, for example, ''patient confined to home,'' ''patient homebound,'' or ''patient in nursing home, no qualified person on duty to draw specimen.'' The manual states that A/B MACs (B) must assure the validity of the annotation through scientific claims samples, as well as through regular bill review techniques. (This could be done by use of the information in A/B MAC (B) files, and where necessary, contact with the ordering physician.) If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, medical necessity criteria in Medicare Benefit Policy Manual, Chapter 15, the manual provides that an educational contact with the ordering physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met. The manual states that the specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.

The Medicare Claims Processing Manual (chapter 16, § 60.1.3) describes specimen drawing for dialysis patients. It states that, with the implementation of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.[111] Clinical laboratory tests for dialysis patients can be performed individually or in predetermined groups on automated profile equipment. The manual states that a specimen collection fee determined by CMS will be allowed only in the following circumstances:

- Drawing a blood sample through venipuncture (that is, inserting into a vein a needle with a syringe or vacutainer to draw the specimen).
- Collecting a urine sample by catheterization.

The manual provides that special rules apply when such services are furnished to dialysis patients. That is, the specimen collection fee is not separately payable for patients dialyzed in the ESRD facility or for patients dialyzed at home. A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements. Payment for specimen collection is included under the ESRD PPS, regardless of whether the laboratory test itself is designated as payable under the ESRD PPS as a renal dialysis service or is separately billable by the ESRD facility with the AY modifier (see Medicare Claims Processing Manual, chapter 16, § 40.6). Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD PPS base rate, may be paid separately.

We believe that the implementation of the ESRD PPS made the specimen collection provision for ESRD beneficiaries in the ESRD facility setting obsolete. That is, prior to the ESRD PPS, ESRD facilities could be paid for laboratory services furnished to ESRD beneficiaries that were considered to be separately payable. Under the prior composite rate system, ESRD facilities with the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification could bill Medicare Part B directly and be paid based on the CLFS for certain laboratory tests, and when appropriate, for a specimen collection fee.[112] In implementing the ESRD PPS, we also implemented consolidated billing requirements in the CY 2011 ESRD PPS final rule (75 FR 49168 through 49173). In that ESRD PPS final rule, we stated that we established these consolidated billing requirements because the ESRD PPS provides an all-inclusive payment for renal dialysis services and home dialysis items and services and the ESRD facility is responsible for all of the renal dialysis services that its patients receive. We further explained that items and services that were paid separately under the basic case-mix adjusted composite rate (such as laboratory tests), would no longer be billed for by other entities (such as laboratories), and therefore, payment for these services would be made only to the ESRD facility so that duplicate payment is not made by Medicare (75 FR 49168).

Additionally, section 1881(b)(14)(B)(i) and (iv) of the Act provides that items and services included in the prior composite rate and other diagnostic laboratory tests not reflected in the composite rate that are furnished to individuals for the treatment of ESRD are renal dialysis services that must be included as part of the ESRD PPS bundled payment. In the CY 2011 ESRD PPS final rule, we explained that

[110] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[111] The manual refers to the Medicare Benefits Policy Manual, Chapter 11, for a description of labortory services included in the composite rate.

[112] Pub. 100–02, Chapter 11, Section 20.0.E.2 and 3. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

patients with ESRD often have comorbid conditions which would require many of the same laboratory tests as those required to monitor a patient's ESRD (75 FR 49168). In that ESRD PPS final rule, we acknowledged that it may be difficult to differentiate between a renal dialysis service laboratory test and tests ordered for non-renal dialysis service conditions. Therefore, to ensure proper payment in all settings, as part of the consolidated billing approach, we provided ESRD facilities and independent laboratories the ability to identify non-renal dialysis service laboratory tests, by using the AY modifier, which allows for separate payment under Medicare Part B (75 FR 49168 through 49169). While this longstanding policy permits ESRD facilities to be paid separately for the non-renal dialysis service laboratory tests, the specimen collection fee is no longer available since staff time used to collect specimens is considered to be a composite rate service (§ 413.171) and therefore payment for specimen collection is made through the ESRD PPS bundled payment to the ESRD facility. Therefore, we believe this section of the manual guidance describing specimen drawing for dialysis patients is no longer applicable, and we would not reflect this policy in regulation and would remove this section of the manual accordingly. We note when an ESRD beneficiary goes to an independent laboratory or a hospital setting, the same payment rules would apply for specimen collection as they would for a non-ESRD beneficiary for that setting.

Lastly, the Medicare Claims Processing Manual (chapter 16, § 60.1.4) includes coding requirements for the specimen collection fees. Specifically, the following HCPCS codes and terminology must be used:

- 36415—Collection of venous blood by venipuncture.
- G0471—Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA).
- P9612—Catheterization for collection of specimen, single patient, all places of service.
- P9615—Catheterization for collection of specimen(s) (multiple patients).

c. Proposal To Codify the Laboratory Specimen Collection Fee Policy in Regulation

As noted previously, most of our laboratory specimen collection fee policies are not reflected in the CLFS regulations. In this section of the proposed rule, we propose the laboratory specimen collection fee policies we would include in regulations.

Section 1833(h)(3) of the Act specifies that payment amounts for the specimen collection fee and travel allowance are ''in addition'' to the payment amounts for CDLTs on the CLFS. As § 414.507 pertains to payment for CDLTs, we believe it is appropriate to create a separate regulation to more clearly reflect that payment for the specimen collection fee and travel allowance is in addition to payment for CDLTs. We are proposing to create a new § 414.523 titled *Payment for laboratory specimen collection fee and travel allowance*. We would specify in § 414.523(a) that in addition to the payment amounts provided for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee and a travel allowance. In § 414.523(a)(1), we would reflect the longstanding specimen collection fee policies described in the manual that continue to be applicable. As noted previously in this proposed rule, we would not reflect in the regulation the specimen collection fee policies that are no longer applicable—specifically, the policies relating to physician eligibility for specimen collection and specimen drawing for dialysis patients—and would remove those policies from the manual.

First, we are proposing that § 414.523(a)(1) would specify that CMS will pay $3 for all specimens collected in one patient encounter. As previously stated in this proposed rule, section 1833(h)(3)(A) of the Act requires the Secretary to provide for and establish a ''nominal fee to cover the appropriate costs in collecting the sample'' for laboratory testing. We have paid $3 as the nominal specimen collection fee amount for several years and at this time we are proposing to maintain the $3 amount. First, the statute specifies that the amount is ''nominal'' and we believe $3 is an appropriate nominal amount to recognize the costs associated with specimen collection. Further, we believe that in enacting section 216(a) of PAMA, Congress recognized CMS's authority to establish the specific nominal fee amount as $3 when it added section 1834A(b)(5) of the Act to increase by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a specimen collected from an individual in a SNF or by a laboratory on behalf of an HHA. We are soliciting comments on our proposal to maintain the $3 nominal specimen collection fee amount, including how this amount could be updated.

Next, we are proposing to move and clarify the provision in our regulations regarding the increased specimen collection fee under section 1834A(b)(5) of the Act, as discussed in the previous paragraph. We implemented this PAMA requirement in a Medicare Change Request (CR) transmittal effective December 1, 2014 (Transmittal #R3056CP; CR #8837) and ultimately finalized this policy in § 414.507(f). [113] The CR provides that, in the case of a specimen collected from an individual in a SNF or from an individual by a laboratory on behalf of a HHA (billed using new HCPCS code, G0471 (Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA))), the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act shall be increased by $2, from $3 to $5, in accordance with section 216(a) of the PAMA. The specimen collection fee is raised from $3 to $5 only when the specimen is being collected by a laboratory technician and when the specimen is from an individual in either a SNF or HHA. We are proposing that this requirement, which is currently reflected in § 414.507(f), would be moved to § 414.523(a)(1)(iv) and would be revised to state that beginning April 1, 2014, for a specimen collected from a Medicare beneficiary in a SNF or on behalf of an HHA, the specimen collection fee otherwise paid under paragraph (a)(1) of § 414.523 is increased by $2.

Next, we are proposing to include in regulation that one specimen collection fee would be allowed for each single patient encounter. This means that, if different types or multiple specimens are drawn from one patient, only one specimen collection fee would be allowed. We believe this policy is consistent with section 1833(h)(3)(A) of the Act, which provides that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter. We propose to reflect this policy in § 414.523(a)(1) by indicating that CMS pays $3 for ''all specimens collected in one patient encounter.''

In § 414.523(a)(1)(i) through (iii), we propose to indicate the specimen collection requirements that must be met for a specimen collection fee to be payable are as follows and described in more detail below. The specimen is:

[113] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3056CP.pdf.*

used to perform a CDLT paid under the CLFS regulations in 42 CFR part 414, subpart G; collected by a trained technician from a Medicare beneficiary who is homebound as described in 42 CFR 424.22(a)(1)(ii) or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; of the following type—blood specimen collected through venipuncture or a urine sample collected by catheterization.

In § 414.523(a)(1)(ii) we are proposing to clarify the requirement that the specimen must be collected by a ''trained technician.'' Section 1833(h)(3) of the Act refers to staff providing specimen collection services as ''trained personnel'' whereas the Medicare Claims Processing Manual, chapter 16, § 60.2 refers to ''the technician.'' The United States Bureau of Labor Statistics (BLS) defines clinical laboratory technologists and technicians as workers who collect samples and also perform tests to analyze body fluids, tissue, and other substances.[114] The term ''laboratory technician'' may not apply to those staff that would generally be providing specimen collection services, as the staff collecting specimens may not also analyze the specimens. Therefore, for the purposes of our Medicare payment policies for specimen collection and travel allowance, we propose to use the phrase ''trained technician'' to refer to the staff providing specimen collection services. We believe this clarification would more closely align the regulatory text pertaining to specimen collection and travel allowance with the statute.

As previously discussed in this proposed rule, Medicare allows payment of a specimen collection fee when it is medically necessary for a trained technician to draw a specimen from either a nursing home patient or homebound patient. Medicare does not allow a specimen collection fee for the technician if a patient in a facility is: (1) Not confined to the facility; or (2) the facility has qualified personnel available to perform the specimen collection. We are proposing to reflect in regulation that the specimen must be collected either from a Medicare beneficiary who is homebound as described in 42 CFR 424.22(a)(1)(ii), or from a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen. We believe this proposed requirement regarding homebound beneficiaries would be consistent with Medicare policy which describes home health services requirements. We are proposing to clarify that payment for specimen collection would only be made to the laboratory when no qualified personnel are available at the inpatient facility to collect the specimen. We believe this proposed clarification would reflect the justification for ''medical necessity'' for purposes of section 1862(a)(1) of the Act. We would reflect this requirement in § 414.523(a)(1)(ii)(B) but would not explicitly state the term ''medically necessary''.

We are proposing to clarify that a specimen collected by a trained technician would have to be either blood collected through venipuncture or a urine collected by catheterization. We would reflect this requirement in § 414.523(a)(1)(iii), which would state that the specimen collection fees are permitted for only these two types of specimens: (1) Blood collected through venipuncture or (2) a urine sample by catheterization. We acknowledge that the manual guidance (described above) uses the terms ''such as'' and ''example'' to describe the types of specimens for which specimen collection fees are paid, which suggests that specimen collections of other than blood and urine are eligible for specimen collection fees. We note, however, that there are only two HCPCS codes for the two types of specimen collections, which means we do not pay, and have not been paying, specimen collection fees for any other types of specimens. Therefore, under our current policy and this proposal, a specimen collection fee would not be payable for any other specimen types, for example, a throat culture or a routine capillary puncture for clotting or bleeding time.

We welcome public comment on the proposed codification and modification of these laboratory specimen collection fee policies. If finalized, we would make conforming changes to the Medicare Claims Processing Manual, Chapter 16, section 60 to reflect changes or clarifications and remove sections that are no longer applicable.

Lastly, we are soliciting comment on specimen collection by physician office laboratories (POLs). As discussed previously in this proposed rule, we are proposing to delete the section in the manual regarding physician specimen collection as codes exist to describe these services when performed by physicians under the PFS. However, we understand that specimens may be collected in the physician's office by POL personnel. As stated in 42 CFR 410.32(d)(1)(iii), Medicare Part B pays for covered diagnostic laboratory tests that are furnished by the office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine. When the physician's office is furnishing CDLTs for its own patients and collecting specimens for those tests, we do not believe this would include specimen collection for homebound or non-hospital inpatients or involve travel for specimen collection, since a POL is not an independent laboratory. However, we seek comments on any possible considerations for the removal of the manual section related to POL specimen collection.

d. Background on the Laboratory Specimen Collection Travel Allowance Policy

Section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample on which a CDLT was performed, except that such a fee may be provided only to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). Like the laboratory specimen collection fee policy discussed in the previous section of this proposed rule, our longstanding policies and instructions regarding the statutory requirements for the CLFS specimen collection travel allowance are described in the Medicare Claims Processing Manual guidance and CRs, currently with no corresponding regulations text. In an August 18, 1993 proposed rule titled ''Medicare and Medicaid: Programs; Payment for Clinical Diagnostic Laboratory Tests,'' we proposed to reflect both the CLFS specimen collection and travel allowance payment policies in regulation (58 FR 43838); however, the proposals therein were not finalized.

As discussed in that proposed rule, due to the variability in time, distance, and wage circumstances in different localities, we implemented the travel allowance under section 1833(h)(3)(B) of the Act by allowing Medicare Administrative Contractors (MACs) discretion in calculating travel allowances. We provided general guidance through our manuals, specifically in the Medicare Claims Processing Manual, chapter 16, § 60.2.[115]

The Medicare Claims Processing Manual guidance at chapter 16, § 60.2 describes two methods for calculating and billing travel allowance for

[114] *https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.*

[115] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf.*

specimen collection. HCPCS code P9603 is used when the average round trip to a beneficiary's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. HCPCS code P9604 is used when the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis. The manual further states that the travel allowance is intended to cover the estimated travel costs for a laboratory technician to travel to collect the specimen and to reflect the technician's salary and travel costs. The travel allowance can be made only where a specimen collection fee is also payable; that is, no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The manual also states that the travel allowance may not be paid to a physician unless the trip to the beneficiary's home, or to the nursing home where the beneficiary resides, was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip. Furthermore, the manual states that the travel allowance is not distributed by CMS. Instead, the MACs (that is, within the claims processing system) calculate the travel allowance for each claim using the rules for the HCPCS codes used for travel allowances, which are P9603—Per Mile Travel Allowance and P9604—Flat Rate.

As described in the manual, the conditions for usage of HCPCS code P9603 are that the minimum ''per mile travel allowance'' is $1.04 (based on CY 2022 instructions). The per mile travel allowance is to be used in situations where the average trip to beneficiaries' homes is farther than 20 miles, and is to be prorated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.

The manual further states that the per mile allowance is computed using the Federal mileage rate (as determined by the Internal Revenue Service (IRS)), plus an additional 45 cents a mile to cover the technician's time and travel costs. For 2022, the Federal mileage rate is 58.5 cents;[116] that amount plus 45 cents equals $1.035, rounded up to $1.04. Contractors have the option of establishing a higher per mile rate in excess of the minimum ($1.04 a mile in CY 2022) if local conditions warrant it. The manual also states that the minimum mileage rate will be reviewed and updated in conjunction with the CLFS as needed and that at no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.[117]

For the flat-rate HCPCS code, P9604, the manual provides the following conditions of usage: CMS will pay a minimum of $10.40 for the flat rate code (HCPCS code P9604, based on CY 2022 instructions), which is the one-way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles. The flat rate travel allowance is to be prorated for more than one blood draw at the same address, and for stops at the homes of Medicare beneficiaries and non-Medicare patients. The laboratory performs the proration calculation when the claim is submitted based on the number of beneficiaries seen on that trip, and the specimen collection fee will be paid for each beneficiary encounter.

The manual states that this rate is based on the assumption that a trip is an average of 15 minutes and up to 10 miles one way and uses the Federal mileage rate (as determined by the IRS) and a laboratory technician's time of $17.66 an hour, including overhead. The manual states that contractors have the option of establishing a flat rate in excess of the minimum of $10.00, if local conditions warrant it, and that the minimum national flat rate will be reviewed and updated in conjunction with the CLFS, as necessitated by adjustments in the Federal travel allowance and salaries. The manual provides examples of the flat rate calculation and describes further MAC flexibilities regarding payment for the CLFS specimen collection travel allowance. The manual also indicates that MACs may use their discretion for the payment of travel allowance in circumstances where the CDLTs are needed on an emergency basis outside the general business hours of the laboratory making the collection. The manual also states that updates to the travel allowance amounts will be issued by CMS via Recurring Update Notification (RUN) on an annual basis.

In summary, the Medicare Claims Processing Manual, chapter 16, § 60.2, indicates that HCPCS code P9603 is used when the average round trip to a beneficiary's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. HCPCS code P9604 is used when the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis. In instances where one trip is made in order to execute specimen draws or pickups from multiple patients, the travel payment component is prorated based on the number of Medicare beneficiaries and non-Medicare patients (not the number of specimens collected) on that trip. All instances of specimen collection and pickups are included in the proration, and the prorated specimen collection travel allowance is billed on behalf of each Medicare patient.

Furthermore, we have provided additional payment instructions through RUN CLFS—Medicare Travel Allowance Fees for Collection of Specimens CRs; the latest being CR 12593,[118] which was issued on January 14, 2022. Consistent with the manual, CR 12593 states that the travel allowance HCPCS codes allow for payment either on a per-mileage basis (P9603) or on a flat-rate per-trip basis (P9604). The CR states that under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), the travel payment component is prorated based on the number of specimens collected on that trip, for both Medicare and non-Medicare patients, either at the time the claim is submitted by the laboratory or when the flat rate is set by the contractor.

CR 12593 states that the Per Mile Travel Allowance (P9603) is to be used in situations where the average trip to the patients' homes is longer than 20 miles round trip and is to be prorated in situations where specimens are drawn from non-Medicare patients in the same trip. For CY 2022, the allowance per mile was computed using the Federal mileage rate of $0.585 per mile plus an additional $0.45 per mile to cover the technician's time and travel costs. The IRS determines the standard mileage rate for businesses based on periodic studies of the fixed and variable costs of operating an automobile, and CMS utilizes this amount for P9604. The CR also states that the Per Flat-Rate Trip Basis Travel Allowance (P9604) is a set fee amount, which is $10.40 for CY 2022.

In summary, CR 12593 states that the travel payment component is prorated based on the number of specimens collected on the trip (and not the number of Medicare and non-Medicare patients), for both Medicare and non-Medicare patients, which differs from the manual instruction which states that the travel allowance should be prorated based on the number of Medicare

[116] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2022.*

[117] The Medicare Claims Processing Manual is available on the CMS website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf.* The manual provides examples of the per-mile travel allowance in section 60.2—Travel Allowance.

[118] *https://www.cms.gov/files/document/r11184cp.pdf.*

beneficiaries and non-Medicare patients (not the number of specimens collected) on that trip.

e. Policy Concerns and Recommendations on the CLFS Specimen Collection Travel Allowance

Laboratories, members of the laboratory industry, and other interested parties have expressed concerns regarding our current CLFS travel allowance payment policy, suggesting that the travel proration methodology is unclear and guidance in the Medicare Claims Processing Manual, payment CRs, and guidance provided by the MACs are conflicting. Additionally, members of the public claim that the travel allowance requirements are administratively complex.

In the CY 2022 PFS proposed rule (86 FR 39310), we requested broad comments on our policies for specimen collection fees and the travel allowance for consideration for possible updates to policies in the future through notice and comment rulemaking. As discussed in the CY 2022 PFS final rule (86 FR 65328), commenters supported clarification to the existing travel allowance policy and also made suggestions regarding possible refinements.

Several commenters described their concerns regarding the current travel allowance policy, stating that the current system requires the individual tracking of miles and paperwork documenting those miles, as well as the calculation of billable charges. Commenters stated that this system creates inconsistencies across facilities providing specimen collection services and creates confusion and burden for health care providers and MACs. One commenter also noted that because of the complex logistics involved in obtaining specimens from homebound patients and non-hospital inpatients and transporting the specimens for prompt processing, a disincentive is created for serving this potentially underserved patient population, leading to potential access issues for Medicare beneficiaries.

Several commenters requested that CMS simplify the travel allowance by creating a single per-encounter flat-rate payment for travel, which would simplify personnel and transportation expenses by eliminating the individual tracking of miles and paper documenting of those miles as well as the calculation of billable charges. The commenters stated that a flat-rate approach would also provide greater consistency across facilities served and reduce the burden on health care providers and MACs, and therefore, further support continued patient access to these laboratory services. A few commenters suggested the creation of a rural add-on payment to provide payment to those laboratories serving Medicare beneficiaries residing in remote areas. Several commenters also stated that the current travel allowance is prone to billing inconsistencies, so simplifying the calculation of the travel allowance would increase the overall understanding of the policy among impacted parties, decrease the instances of health care providers inadvertently overbilling for mileage, reduce program integrity concerns, and improve clarity for all parties involved.

Several commenters also recommended that business requirements outlined in the annual Medicare travel allowance CR be updated to require the contractor to search their files to adjust claims already paid at the prior year travel allowance rather than require action by laboratories. The commenter requested that contractors be instructed to review claims and reprocess at the updated rates rather than require laboratories to initiate the revisions.

Additionally, the OIG issued an August 25, 2021 report, CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances (A–06–20–04000),[119] in which the OIG discussed ongoing concerns regarding the Medicare CLFS travel allowance policy and summarized findings from previous audits of MACs in which claims for phlebotomy travel allowances were paid using incorrect prorated mileage and claims for phlebotomy travel allowances were paid using incorrect payment rates. The OIG also described instances in which health care provider documentation was insufficient to warrant payment of the phlebotomy travel allowances.

The 2021 OIG report presented recommendations to CMS regarding the CLFS travel allowance policy, including working with the MACs to educate health care providers about the documentation requirements for specimen collection travel allowances, instructing the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate, and issuing regulations related to phlebotomy travel to clarify various aspects of the travel allowance payment policy.

In the CY 2022 PFS proposed rule (86 FR 39310 through 39311) and CY 2022 PFS final rule (86 FR 65328), we discussed the travel allowance policy and stated that we made permanent the option for laboratories to maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic documentation applies to specimen collection for any CDLT. We noted that laboratories will need to be able to produce electronic documentation in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for submission of this information if necessary. We believe that this flexibility to maintain electronic documentation of miles traveled provides clarity to laboratories about documentation requirements for the Medicare CLFS travel allowance for specimen collection payment policy.

Additionally, we have instructed the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate, thereby addressing the OIG's and commenters' suggestions regarding reprocessing using the updated rates through the revision of business requirements in the January 14, 2022 RUN CLFS—Medicare Travel Allowance Fees for Collection of Specimens CR 12593.[120] The OIG and commenters alike recommended that we update the business requirements outlined in the annual Medicare travel allowance CR to require the MACs to search their files to adjust claims already paid at the prior year's travel allowance amount rather than require action by laboratories. Specifically, in the CR, we included the Business Requirement 12593.5, which states that ''Contractors shall adjust previously paid travel allowance claims with dates of service on or after January 1, 2022, in order to apply the updated payment rate and initiate those adjustments within 60 days, if claims are paid at the prior year's rates before the new rate is entered into the MACs' systems.'' We believe this modification to the business requirements will eliminate the need for action by laboratories for adjustments to claims and instead provide instruction to contractors to review claims and reprocess at the updated rates as appropriate.

f. Proposed Codification and Modifications of the CLFS Specimen Collection Travel Allowance Policy

In light of the concerns from the public, and in an effort to respond to the OIG's recommendation that CMS issue regulations regarding certain aspects of

[119] *https://oig.hhs.gov/oas/reports/region6/62004000.asp.*

[120] *https://www.cms.gov/files/document/r11184cp.pdf.*

the travel allowance for specimen collection payment policy, we are proposing to codify in our regulations, and make certain modifications and clarifications to, the Medicare CLFS travel allowance policies, as described below. We believe these proposals would achieve CMS' aims of simplifying and clarifying our travel allowance policies. We propose to add §414.523(a)(2), ''Payment for travel allowance,'' to reflect the requirements for the travel allowance for specimen collection. Specifically, in accordance with section 1833(h)(3)(B) of the Act, we are proposing to include in our regulations the following: (1) General requirement, (2) travel allowance basis, (3) travel allowance amount, and (4) travel allowance amount calculation.

Section 1833(h)(3)(B) of the Act states that the Secretary shall provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample. We believe this language indicates that only instances of specimen collection requiring trained technicians [121] for the purposes of collecting the sample are to be included in the travel allowance calculation. Therefore, travel for simple pickup of specimens or for specimen collection that does not require the services of trained technicians should not be considered in the calculation of the travel allowance. This means, the travel allowance may be paid only if a specimen collection fee is also payable; for example, no travel allowance would be paid if a trained technician merely performs a messenger service to pick up a specimen drawn by other technicians.

The Medicare Claims Processing Manual, chapter 16, § 60.2 states, ''The additional allowance can be made only where a specimen collection fee is also payable, *i.e.,* no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel.'' We propose to codify this general requirement at § 414.523(a)(2)(i). This provision would state that CMS pays a travel allowance where the specimen is one for which a specimen collection fee is paid and would make clear that all of the requirements for the specimen collection fee to be paid (which are specified in § 414.523(a)(1)) would need to be met for the travel allowance to be payable.

[121] As noted previously in this section of the proposed rule, we are proposing to use the term ''trained technician'' for purposes of our specimen collection fee and travel allowance policies.

Additionally, section 1833(h)(3)(B) of the Act states that the travel allowance may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). We interpret this statutory language to mean that the fee only applies when a trained technician draws a specimen from a patient who either is in an inpatient facility that is not a hospital or is a homebound patient. (A discussion regarding the definition of a homebound patient is provided in section III.B.6.b. of this proposed rule.) The Medicare Claims Processing Manual, chapter 16, § 60.2 states that ''Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient''. We believe it is appropriate to codify that the travel allowance is permitted only where the individual from whom the specimen is collected is homebound or is an inpatient in an inpatient facility (other than a hospital). This requirement would be reflected at § 414.523(a)(2), which as we note above would require all of the specimen collection fee requirements at § 414.523(a)(1) to be met, and which would include the proposed requirement at § 414.523(a)(1)(ii) that the specimen is collected from a Medicare beneficiary who is homebound as described in 42 CFR 424.22(a)(1)(ii) or a non-hospital inpatient.

In addition to proposing to codify the general requirement for travel allowance, we are also proposing to clarify and make modifications to the methodology for and the calculation of the CLFS travel allowance amounts. In accordance with section 1833(h)(3)(B) of the Act, we are proposing to reflect the travel allowance payment methodology in the regulations and include the following components: (1) travel allowance basis, (2) travel allowance amount, and (3) travel allowance amount calculation.

In § 414.523(a)(2)(ii), we are proposing to codify and clarify that CMS pays a travel allowance on the following bases: (1) flat-rate travel allowance basis and (2) per-mile travel allowance basis. We interpret the statutory language in section 1833(h)(3)(B) of the Act that requires us to pay a fee for trained personnel to travel to the location of an individual to collect the sample to mean that the travel allowance fee is only applicable to travel that is for the purpose of collecting the specimen from a Medicare beneficiary. To that end, we believe only one travel allowance payment may be made for specimen collection for a Medicare beneficiary based on the beneficiary's location, and only when a Medicare beneficiary requires the collection of a specimen necessary for performance of CDLTs. We believe that non-Medicare patients should not be included in any portion of the calculation of the travel allowance. This interpretation would be a modification to existing guidance in the Medicare Claims Processing Manual, chapter 16, § 60.2, which states that the travel allowance ''is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.'' This modification would reflect that we believe only Medicare patients should be considered in the calculation and payment of the travel allowance, which would more closely align with the statutory language regarding ''the location of an individual,'' that is, the location of a Medicare beneficiary receiving specimen collection services. We also believe this modification would address concerns from laboratories, the OIG, and other interested parties who requested clarification regarding the inclusion of Medicare and non-Medicare beneficiaries in the travel allocation calculation.

We are proposing that, whether a laboratory bills the flat-rate travel allowance basis or the per-mile travel allowance basis would depend upon the total miles traveled and number of locations. Section 1833(h)(3)(B) of the Act states, in establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample. Therefore, we believe a key component of the travel allowance payment for specimen collection is the number of miles traveled for the specimen collection.

In considering potential methodologies for calculating a travel allowance for specimen collection, we conducted an analysis of the usage of the existing Per Mile Travel Allowance HCPCS code (P9603) to understand the usage of P9603 and analyze the billing of miles related to travel allowance for specimen collection. In CY 2019, among professional and institutional Medicare claims, there were approximately 3.2 million total claim lines billed for HCPCS code P9603 (per-mile travel allowance). Among the P9603 claim lines, the average mileage billed per claim line was 18.8 with a standard

deviation of 33.4. However, the median distance traveled per line was 7 miles. Of all P9603 claim lines, 76.3 percent were billed with less than 20 miles, and 37.9 percent of all P9603 claim lines were billed with less than five miles. The average payment per line for P9603 in CY 2019 was $18.13; however, the median payment per line was $6.09. Additionally, our analysis also shows that 23.7 percent of miles traveled were greater than 20 miles, with 150,442 claim lines of the approximately 3.2 million total claim lines, or 4.7 percent, logging more than 85 miles per trip. We believe that these long-distance trips likely reflect specimen collection from beneficiaries in rural areas (which are generally underserved zones). Given that the majority of P9603 claim lines (76.3 percent) are billed with less than 20 miles, we believe that 20 miles would be an appropriate threshold for use in the travel allowance bases for specimen collection. In addition, to address concerns about administrative complexity, we are proposing that the flat-rate travel allowance basis only would be available for trips involving one location.

Specifically, we are proposing in § 414.523(a)(2)(ii)(A) that the flat-rate travel allowance basis would apply when the trained technician travels 20 eligible miles or less to and from one location for specimen collection from one or more Medicare beneficiaries. We discuss our proposal for calculating eligible miles below. As discussed previously in this section of the proposed rule, we believe that section 1833(h)(3) of the Act supports payment for specimen collection and travel allowance for only Medicare beneficiaries and should not include non-Medicare beneficiaries. Under this proposal, laboratories would bill Medicare using existing HCPCS code P9604 to receive payment for the flat-rate travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid, which we discuss more fully in the travel allowance amount calculation proposal below. We believe that providing payment for the flat-rate travel allowance basis we are proposing would serve to simplify the administrative requirements for laboratories in terms of billing and record-keeping activities. Additionally, our proposed clarification regarding requirements for proration would address issues raised by interested parties, including the OIG, who expressed concerns regarding inconsistencies in current guidance. We are seeking comment on considerations related to the flat-rate travel allowance basis, including considerations for proposed distance, alternatives for a possible flat-rate travel allowance basis, as well as the utility of this basis or the potential exclusion of this basis for the purposes of the travel allowance for specimen collection.

In addition to the flat-rate travel allowance basis, we are proposing in § 414.523(a)(2)(ii)(B) the per-mile travel allowance basis, which would apply when the trained technician travels more than 20 eligible miles to and from one location for specimen collection from one or more beneficiaries or when the trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary. To be clear, this proposed basis would apply in two circumstances—where round trip travel to one location is greater than 20 eligible miles and where travel is to more than one location, regardless of the number of miles traveled. We are proposing to modify our per-mile travel allowance policy in this way for greater clarity, administrative simplification, and consistency with statute. Under this proposed travel allowance basis, the laboratory would receive payment for the total number of miles traveled for specimen collection, which would be allocated to each Medicare beneficiary for whom a specimen collection fee is paid. We believe this proposal would serve to address the OIG's recommendations that CMS clarify various aspects of the travel allowance payment policy, including requirements for proration, which we discuss more fully in the travel allowance amount calculation proposal below. We seek comment on all aspects of the proposed per-mile travel allowance basis.

Additionally, we are proposing to specify travel allowance amount requirements pertaining to eligible miles and the travel allowance mileage rate. In § 414.523(a)(2)(iii)(A), we propose that eligible miles would begin at the laboratory and end at the laboratory where the trained technician returns the specimen(s) for testing. We believe the laboratory is the most likely place where the trained technician would become aware of the laboratory order and acquire the necessary supplies to perform the specimen collection. Although we do not believe the trained technician would commence travel related to specimen collection from a location other than the laboratory, we seek comment as to whether there are alternative starting locations we should consider. This proposed provision, requiring that the mileage calculation begins at a laboratory, would codify existing policy in the Medicare Claims Processing Manual, chapter 16, § 60.2, which provides several examples of travel allowance scenarios that reference the start of a travel allowance route as beginning at a laboratory, and would be consistent with section 1833(h)(3)(B) of the Act.

We are further proposing in § 414.523(a)(2)(iii)(A) that eligible miles would not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons. We believe the statutory language in section 1833(h)(3)(B) of the Act supports our proposal to exclude from the calculation of eligible miles any miles traveled to a location where no specimens are collected, to the location of a non-Medicare beneficiary for specimen collection, to a Medicare beneficiary where no specimen collection occurs, or for personal purposes. This proposed provision would codify the Medicare Claims Processing Manual, chapter 16, § 60.2, which states that ''the travel allowance is intended to cover the estimated travel costs of collecting a specimen.''

In § 414.523(a)(2)(iii)(B), we are proposing to set forth the travel allowance mileage rate, which would be used in the travel allowance amount calculations discussed below. Section 1833(h)(3)(B) of the Act requires the travel allowance to cover both the ''transportation'' and ''personnel expenses'' for trained personnel to travel to the location of an individual to collect a sample. Our proposed travel allowance mileage rate therefore would reflect both of these components.

As described previously in this section of the proposed rule, we currently issue annual travel allowance amounts through CR publications, such as CR 12593.[122] Currently, CMS adds the Internal Revenue Service (IRS) standard mileage rate to an additional $0.45 per mile, which is intended to pay for the trained personnel's time, as described in CR 12593, where the additional $0.45 per mile addresses time and travel costs required by the technician for approximately 15 minutes of labor. The manual states that this rate is based on the assumption that a trip is an average of 15 minutes and up to 10 miles one way and uses the Federal mileage rate (as determined by the IRS) and a technician's time of $17.66 an hour, including overhead. For CY 2022, the IRS standard mileage rate is $0.585. That amount plus $0.45 for the trained personnel's labor yields a

[122] *https://www.cms.gov/files/document/r11184cp.pdf.*

travel allowance mileage rate of $1.035, which is rounded up to $1.04 for CY 2022. We are proposing to codify the travel allowance mileage rate in regulation as well as modify and clarify certain aspects of it.

The IRS updates and issues standard mileage rates on a periodic basis, generally annually.[123] These rates are used to calculate the deductible costs of operating an automobile for business, charitable, medical, or moving for the purpose of calculating Federal taxes. We are proposing that the ''transportation'' component of the travel allowance mileage rate would equal the IRS standard mileage rate, which would be consistent with our current policy. We believe using the IRS standard mileage rate would continue to be an appropriate way to cover transportation as the IRS rate accounts for the costs associated with transportation per mile traveled. We seek comment on our proposal to use the IRS standard mileage rate to cover the transportation component of the travel allowance mileage rate.

In addition, we are proposing to include an amount to cover the ''personnel expenses'' component of the travel allowance mileage rate where the trained technician's personnel expenses would be based on a wages-per-mile amount. First, we are proposing that personnel expenses are wages in this context, where wages would represent the cost of the trained technician's time for traveling to collect the sample. We are proposing to base the specific wage amount on data from the BLS, which publishes salary statistics for occupations in the United States. The BLS defines a phlebotomist as a professional who draws blood for tests, transfusions, research, or blood donations.[124] The BLS separately defines clinical laboratory technologists and technicians as workers who collect samples and perform tests to analyze body fluids, tissue, and other substances.[125] For purposes of the travel allowance, we believe the BLS definition of phlebotomist more closely aligns with the trained technicians that we believe are providing the types of specimen collection services described earlier in this section, as a phlebotomist typically draws blood or other specimens, while a laboratory technologist may both collect the specimen as well as analyze the specimen. We do not believe that trained technicians collecting the specimen for the purposes of our specimen collection policies are also analyzing the specimens. Therefore, we propose to use wage data in the BLS-defined category of phlebotomist to establish the personnel expense component of the travel allowance mileage rate.

For CY 2021, (the latest available information), the BLS states that the median pay (or the wage at which half of the workers in the occupation earned more than that amount and half earned less) for phlebotomists is $17.97 per hour.[126] To account for the personnel expenses associated with travel for specimen collection, we propose to use the latest available published figure for the median hourly wage amount for phlebotomists, which is published by the BLS, for the purposes of annually updating the travel allowance amount for specimen collection. We propose to codify this aspect of the travel allowance mileage rate at § 414.523(a)(2)(iii)(B) by describing that the travel allowance mileage rate includes an amount to cover expenses for a trained technician equal to the most recent median hourly rate for phlebotomists, as published by the BLS. This approach would be a clarification of and modification to current guidance, as CR 12593 describes that the $0.45 per mile added to the IRS rate is meant to address the trained personnel's time and travel costs by the technician based on approximately 15 minutes of labor.

Next, we would calculate a per-mile amount to derive the approximate number of miles traveled by the trained technician each hour. To do this, we are proposing to use an average driving speed. The average miles-per-hour driving speed would be multiplied by the trained technician's estimated wages, as described above, and the result would be an amount that represents wages per mile, which would be the personnel expenses associated with travel for specimen collection. We are proposing to use an average driving speed of 40 miles per hour, as we believe most of the travel related to specimen collection would be performed in local and residential areas, as our data show that the median number of miles traveled for specimen collection is approximately 7 miles.

Therefore, to establish the personnel expenses component of the travel allowance mileage rate, which would be a per-mile amount, we propose that we would divide the most recent median hourly wage for phlebotomists, as published by the BLS, by 40 to represent an average miles-per-hour. We propose to codify this aspect of the travel allowance mileage rate at § 414.523(a)(2)(iii)(B). For CY 2023, the amount would be equal to the most recent BLS median hourly wage for a phlebotomist of $17.97 per hour (which is currently the BLS CY 2021 rate) divided by 40, which is $0.45 per mile. This amount is consistent with the amount that we add to the IRS rate under our current travel allowance policy.

In summary, we propose to establish in 414.523(a)(2)(iii)(B) that the travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the BLS, divided by 40 to represent an average miles-per-hour driving speed. The travel allowance mileage rate would be updated annually using the most recent IRS and BLS information, which we would issue in subregulatory guidance annually through CRs.

We seek comment on all aspects of this proposed travel allowance mileage rate, including the use of the IRS standard mileage rate to cover transportation, the proposed use of estimated wages and average driving speed to cover personnel expenses, and other specific considerations or alternatives for establishing this rate.

Finally, we are proposing to include in § 414.523(a)(2)(iii)(C) the travel allowance amount calculations for the flat-rate travel allowance basis and the per-mile travel allowance basis discussed previously in this section of the proposed rule. We believe that these proposed calculations would be a modification to existing guidance, as we would clarify and revise the travel allowance amount calculations in several respects.

In our analysis of mileage traveled for the purposes of specimen collection, described above, the results indicate that the median mileage per trip for specimen collection per Medicare beneficiary is approximately 7 miles; therefore, we believe that a reasonable approximation of the typical mileage required for specimen collection per beneficiary is about 10 miles. As such, for the flat-rate travel allowance basis, we are proposing in § 414.523(a)(2)(iii)(C)(1) that the travel allowance amount is the travel allowance mileage rate described above multiplied by ten (10) (for CY 2023 example purposes, this amount would be $10.40) and divided by the number of beneficiaries for whom a specimen

[123] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2022.*

[124] *https://www.bls.gov/ooh/healthcare/phlebotomists.htm.*

[125] *https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.*

[126] *https://www.bls.gov/ooh/healthcare/phlebotomists.htm.*

collection fee is paid. Dividing by the number of beneficiaries for whom a specimen collection fee is paid would ensure that the flat-rate travel allowance amount is apportioned to each beneficiary receiving specimen collection services and that payment is calculated in a operationally feasible manner, as a laboratory must submit a claim for each beneficiary to receive payment for travel allowance; this would allow for a fixed payment amount to be straightforwardly apportioned to the number of beneficiaries for whom a specimen collection fee is paid in a single location. We believe this proposed flat-rate travel allowance calculation would simplify payment for travel to one location for specimen collection services requiring travel of 20 miles or less, which would ease administrative burden.

Additionally, this proposed methodology would be consistent with the existing flat-rate travel allowance payment policy described in CR 12593 and would clarify the proration methodology.

For an example of the proposed flat-rate travel allowance calculation, consider a situation in which a trained technician travels seven (7) miles from the laboratory to a nursing home to collect blood specimens collected through venipuncture from five patients, four of whom are Medicare beneficiaries. The trained technician collects three specimens from Medicare beneficiaries, collects one specimen from the non-Medicare patient, and simply picks up a previously collected specimen from one Medicare beneficiary. The trained technician then drives seven (7) miles back to the laboratory to deliver the specimens without making any other stops. The trained technician has provided specimen collection services to three Medicare beneficiaries. One Medicare beneficiary did not require specimen collection services, and therefore, a specimen collection fee would not be payable. In this example, the laboratory would use the flat-rate travel allowance basis because the trained technician traveled a total of 14 miles. To calculate the travel allowance mileage rate, the laboratory would divide flat-rate travel allowance amount of $10.40 by the number of beneficiaries for whom a specimen collection fee is paid (three beneficiaries), which equals $3.47. To bill for the travel allowance, the laboratory would submit one claim for each beneficiary for whom a specimen collection fee is paid by billing HCPCS code P9604.

We propose that updates travel allowance mileage rates would be issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. We seek comment on all aspects of the proposed calculation of the flat-rate travel allowance amount, including considerations for the proposed mileage factor of ten (10) and the proposed proration by the number of beneficiaries for whom a specimen collection fee is paid.

We are also proposing to clarify, modify, and codify in regulation the calculation for the per-mile travel allowance amount. Under proposed § 414.523(a)(2)(iii)(C)(2), the per-mile travel allowance amount would equal the number of eligible miles multiplied by the travel allowance mileage rate discussed above, divided by the number of beneficiaries for whom a specimen collection fee is paid.

As discussed previously in this section of the proposed rule, we believe that section 1833(h)(3) of the Act supports payment for specimen collection and travel allowance only for Medicare beneficiaries, and we are proposing that the per-mile travel allowance amount calculation would only consider the number of Medicare beneficiaries from whom specimens are collected in the proration of the per-mile travel allowance. As the current policy in manual guidance and the CR factor are inconsistent in referring to the number of specimens or number of patients, our proposal would be a policy change to clarify that only the number of Medicare beneficiaries for whom a specimen collection fee is paid should be included in the calculation.

To calculate the per-mile travel allowance amount, the laboratory would first calculate the total number of eligible miles, as set forth in proposed § 414.523(a)(2)(iii)(A), the trained technician traveled—this would be the total number of miles traveled by the trained technician to locations where one or more Medicare beneficiaries received specimen collection services and back to the laboratory where the technician returns the specimen(s) for testing. The eligible miles would be multiplied by the travel allowance mileage rate as set forth in proposed § 414.523(a)(2)(iii)(B), then divided by the number of beneficiaries for whom a specimen collection fee is paid, which would yield a prorated travel allowance amount. Under this proposed approach, the laboratory would receive payment for the total number of eligible miles traveled for specimen collection, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid. The laboratory would then submit a claim billing HCPCS code P9603 for payment of the per-mile travel allowance amount for each beneficiary for whom a specimen collection fee is paid. We believe this proposed calculation for the per-mile travel allowance basis would resolve concerns raised by the public about inconsistent guidance.

For an example of the per-mile travel allowance amount calculation, consider a trained technician traveling 45 miles from a laboratory in a city to a rural SNF, collecting blood specimens through venipuncture from 6 Medicare beneficiaries, and then driving 45 miles to return to the laboratory. In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled more than 20 eligible miles to one location for specimen collection. To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles traveled to the location of Medicare beneficiaries receiving specimen collection services, which, in this case is 45 miles from the laboratory to the SNF and 45 miles from the SNF returning to the laboratory, for a total of 90 eligible miles. The eligible miles would then be multiplied by the travel allowance mileage rate of $1.04, yielding a total of $93.60. This total amount would then be prorated by dividing by the number of Medicare beneficiaries for whom a specimen collection fee is paid (6), yielding a per-beneficiary amount of $15.60 ($93.60/6 = $15.60). To bill for the travel allowance, the laboratory would submit one claim for each beneficiary in the amount of $15.60 HCPCS code P9603.

In another example, a trained technician travels 40 miles from a laboratory to the location of a Medicare beneficiary to collect a specimen, then travels 10 miles to the location of a non-Medicare patient to collect a blood specimen through venipuncture, then travels 20 miles to the location of two Medicare beneficiaries to collect urine specimens by catheterization, and then travels 20 miles to return to the laboratory. In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled to more than one location for specimen collection. To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles, which would include the miles traveled from the laboratory to the locations of Medicare beneficiaries to collect specimens plus the miles back to the laboratory for specimen drop-off. Eligible miles would not would not include the 10 miles traveled to the

location of the non-Medicare patient to collect a specimen, but would include the 40 miles traveled from the laboratory to the location of the first Medicare beneficiary, the 20 miles to the location of the two Medicare beneficiaries, and the return trip to the laboratory of 20 miles, for a total of 80 eligible miles. The eligible miles would then be multiplied by the travel allowance mileage rate of $1.04, yielding a total of $83.20. This total would then be prorated by dividing by three (3) Medicare beneficiaries for whom a specimen collection fee is paid, yielding an amount of $27.73. The laboratory would then submit a claim using HCPCS code P9603 for travel allowance for each of the Medicare beneficiaries in the amount of $27.73. Again, the laboratory receives payment for the eligible miles traveled by the trained technician, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid.

In conclusion, the proposed travel allowance payment policies would represent both modifications to and clarifications of the specimen collection travel allowance payment methodologies currently described in guidance. We believe these proposed changes and clarifications, if finalized, would improve and simplify the administration of the travel allowance payment policy. Laboratories would use HCPCS code P9604 to bill for the flat-rate travel allowance basis for shorter trips to one location, and HCPCS code P9603 to bill for the per-mile travel allowance basis for longer trips to one location and trips to multiple locations, which we believe would ensure payment for specimen collection services based upon eligible miles required for such travel and address concerns of interested parties about the provision of specimen collection services for individuals residing in remote locations.

We seek comment on all aspects of this travel allowance proposal, including the proposed general requirement, the proposed provisions regarding the flat-rate and the per-mile travel allowance bases and the utility of having both approaches, the proposed provisions regarding eligible miles and the travel allowance mileage rate, as well as considerations for the methodologies to calculate the travel allowance amounts. We also seek comments on possible alternative considerations for the CLFS travel allowance, including suggestions based on private-payor and/or other approaches for tracking mileage and paying for travel allowance, including per-beneficiary per-encounter bases, or other approaches for providing payment for travel for specimen collection. We note that our proposed regulations would not require MACs to calculate travel allowance payments, nor would they reflect the MAC flexibilities with respect to travel allowance payment that are currently in guidance, such as their discretion to pay the travel allowance in circumstances where CDLTs are needed on an emergency basis; we seek comment on this issue as well.

We would make conforming changes to the Claims Processing Manual, Chapter 16, section 60 to reflect these proposed travel allowance policies, if finalized, including any changes or clarifications. As noted previously, we would remove sections of the manual containing policies that are no longer applicable.

D. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Act), regulation (42 CFR 410.37), and National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). The statute and regulations expressly authorize the Secretary to add other tests and procedures (and modifications to tests and procedures) for colorectal cancer screening with such frequency and payment limits as the Secretary finds appropriate based on consultation with appropriate organizations. (Section 1861(pp)(1)(D) of the Act; § 410.37(a)(1)(v)). For a number of CRC screening tests, the statute at section 1834(d) of the Act established frequency and payment limits restricting coverage to individuals at least 50 years of age. We are proposing to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation to 45 years in our regulations at § 410.37 and in NCD 210.3. Our proposal would align our coverage with a recently revised recommendation by the United States Preventive Services Task Force (USPSTF) for certain CRC tests as permitted by section 1834(n) of the Act. Moreover, after consulting with appropriate organizations, we are also proposing to modify the payment limitation for other CRC screening tests identified in § 410.37 and in NCD 210.3 to permit coverage for individuals to begin at age 45.

In addition, we propose to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Historically, CMS has viewed a colonoscopy after a positive non-invasive stool-based CRC screening test to be a diagnostic colonoscopy. In recent years, the clinical recommendations and guidance of medical professional societies and screening experts have evolved for stool-based colorectal cancer screening due to a number of factors including the relative number of false positive results, low follow-up colonoscopy rates and patient access barriers. For example, the positive predictive value of a FIT (fecal immunochemical test) (the likelihood that an individual with a positive FIT test result actually has colorectal cancer) reportedly varies widely from 8 to 21 percent depending on the test and testing center.[127] Importantly, recent published evidence has again highlighted that individuals that did not get a follow-up colonoscopy were about twice as likely to die of colorectal cancer compared to individuals that did have one.[128] Since the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allow for early detection and treatment and reduce cancer mortality, the follow-up colonoscopy is integral to non-invasive stool-based CRC screening since improvements in health outcomes would not be possible without the follow-up. Medical professional organizations and clinical experts have reached consensus based on the evidence on this recommendation. In May 2021 USPSTF revised their evidence-based recommendation to include the statement ''Positive results on stool-based screening tests require follow-up colonoscopy for the screening benefits to be achieved.'' [129] Accordingly, we propose to modify CRC screening tests within our authority in consultation with appropriate organizations. The outcome of our more appropriate and complete approach to CRC screening will be that beneficiary cost sharing for the initial screening stool-based test and the follow-on screening colonoscopy test would not apply and that they are both tests paid at 100 percent (no applicable copayment percentage) as specified screening services under the Act. The issue of

[127] Nielson CM, Petrik AF, Jacob L, et al. Positive predictive values of fecal immunochemical tests used in the STOP CRC pragmatic trial. Cancer Med. 2018;7(9):4781–4790. doi:10.1002/cam4.1727.

[128] Zorzi M, Battagello J, Selby K, et al. Non-compliance with colonoscopy after a positive faecal immunochemical test doubles the risk of dying from colorectal cancer. Gut. 2022;71(3):561–567. doi:10.1136/gutjnl-2020-322192.

[129] *https://ww.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

when the follow-on screening colonoscopy involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test would not change from current policy and is described later in our proposal. We believe this new understanding will encourage the wider utilization of non-invasive CRC screening tests and reduce barriers to screening, prevention and early detection of CRC.

Our proposals will update Medicare coverage and payment policies to align with our new understanding of CRC screening. We believe these proposals will expand access to quality care and improve health outcomes through prevention, early detection, more effective treatment and reduced mortality. Moreover, they would directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC.

Our proposals also directly support President Biden's Cancer Moonshot Goal to cut age-adjusted death rate from cancer by at least 50 percent and addresses his recent Proclamation of March as National Colorectal Cancer Awareness Month. The proclamation stated that ''early stages of colorectal cancer often emerge without symptoms, and it is important to begin regular screenings starting at the age of 45.'' It goes on to read ''Thanks to the Affordable Care Act, most health insurance plans must cover certain preventive services with no out-of-pocket costs. This coverage now includes colorectal cancer screenings for adults over the age of 45, making it easier to get colorectal cancer screenings and helping improve access to earlier treatment.'' [130]

1. Background

In CY 2019, the last year for which incidence data are available, CRC accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[131] The National Cancer Institute estimates that in 2021, 149,500 individuals will be newly diagnosed with CRC and 52,980 individuals will die from CRC in the United States.[132] The Center for Disease Control and Prevention (CDC) advises, ''Colorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. . . . Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [133]

Rural communities and communities of color are especially impacted by the incidence of CRC. A CDC study found the death rate of CRC (per 100,000) to be 17.1 in rural nonmetropolitan counties verses 14.0 in metropolitan counties with populations greater than 1 million.[134] African Americans experience both new cases and deaths from colorectal cancer at rates significantly above those of all races.[135] An article in the American Journal of Pathology states African Americans also are often diagnosed at a younger age (median ages, 66 and 70 years for African American men and women compared with 72 and 77 years for white men and women, respectively). Moreover, African Americans are two times more likely to be diagnosed with CRC before the age of 50 years, which justified the recommendation to begin endoscopic screening at the age of 45 years instead of 50 years.[136]

In May 2021, the USPSTF issued a revised Final Recommendation Statement on CRC Screening. This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC Screening. In terms of health disparities in CRC and CRC screening, the May 2021 revised USPSTF statement reads, ''The causes for these health disparities are complex; recent evidence points to inequities in the access to and utilization and quality of colorectal cancer screening and treatment as the primary driver for this health disparity rather than genetic differences . . . Black adults across all age groups, including those younger than 50 years, continue to have higher incidence of and mortality from colorectal cancer than White adults.'' [137]

In addition to reducing the minimum age for Medicare payment for CRC screening test payment, we are proposing to address a longstanding barrier and disincentive to CRC screening using a non-invasive stool-based test as a first step of a complete screening. Examples of Medicare covered non-invasive stool-based CRC screening tests include a guaiac-based fecal-occult blood test (gFOBT) described in regulation at § 410.37(a)(2)(i) and in National Coverage Determination 210.3 Colorectal Cancer Screening Tests, as well as immunoassay-based fecal-occult blood test (iFOBT) and the Cologuard™—Multitarget Stool DNA (sDNA) test described in NCD 210.3. For the best health outcomes (CRC prevention and early detection), it is important that patients receive a complete CRC screening.

In recent years, government bodies and professional societies have reconsidered their understanding of a complete CRC screening and now consider CRC screening incomplete for individuals with a positive result on a stool-based test until a follow-on screening colonoscopy is also completed. The National Colorectal Cancer Roundtable recommends that the patient should only be counted as having completed the CRC screening process after a colonoscopy is performed.[138] Under current Medicare policies, if a Medicare patient initially receives a positive result from a non-invasive and less burdensome screening stool-based CRC test, the test would be viewed as showing signs or symptoms of colorectal cancer. If a beneficiary received a subsequent colonoscopy, we viewed the test as a diagnostic procedure and normal cost sharing rules for diagnostic test would apply. Our current policy, however, may discourage patients from seeking a follow-on colonoscopy because of the Medicare cost-sharing. A 2018 guideline update from the American Cancer Society on CRC screening for average-risk adults reads ''Trials offering a choice between a stool test and a

[130] *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/02/28/a-proclamation-on-national-colorectal-cancer-awareness-month-2022/.*

[131] *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[132] *https://seer.cancer.gov/statfacts/html/colorect.html.*

[133] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

[134] Henley SJ, Anderson RN, Thomas CC, Massetti GM, Peaker B, Richardson LC. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties—United States. MMWR Surveill Summ 2017;66(No. SS-14):1–13. DOI: http://dx.doi.org/10.15585/mmwr.ss6614a1.

[135] *https://seer.cancer.gov/statfacts/html/colorect.html.*

[136] Augustus GJ, Ellis NA. Colorectal Cancer Disparity in African Americans: Risk Factors and Carcinogenic Mechanisms. Am J Pathol. 2018;188(2):291–303. doi:10.1016/j.ajpath.2017.07.023.

[137] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[138] *http://nccrt.org/wp-content/upload/0305.60-Colorectal-Cancer-Manual_FULFILL.pdf.*

structural examination compared with either test alone have generally demonstrated greater uptake when a choice is offered. The best evidence in the United States derives from a randomized trial in a safety-net population comparing annual gFOBT versus colonoscopy versus choice between the 2 in which it was demonstrated that choice was more effective than offering colonoscopy alone. In the first year of the study, which included patient navigation (year 1 only), the screening completion rate was 38% for patients offered colonoscopy, 66 percent for those offered gFOBT, and 68 percent for those offered a choice. While uptake overall was similar in the gFOBT group versus the choice group, it is clear that a ''colonoscopy-only'' referral resulted in substantially lower adherence.'' [139]

One of the goals of CRC screening is to enable the healthcare system to identify patients who need treatment early enough to prevent or treat the condition most effectively. In order to encourage patients to obtain a follow-on colonoscopy, a number of appropriate organizations have suggested that we adopt a new approach that looks at colorectal cancer screening as a continuum in the scenario where an initial stool-based test returns a positive result and includes a follow-on screening colonoscopy, when determined appropriate by the patient and the healthcare provider. There currently exists a misalignment of applicable patient cost sharing for a follow-on screening colonoscopy after a positive non-invasive stool-based test as Medicare coverage policies have not yet been updated to align to this new understanding of a complete CRC screening described earlier. If the patient had chosen the more expensive, invasive and burdensome screening colonoscopy as the first step in their CRC screening, there would be no applicable beneficiary cost sharing for the screening colonoscopy. However, under current policy, if the patient initially receives a positive result from a non-invasive, less burdensome and less expensive stool-based test as the first step in their CRC screening, beneficiary cost sharing would not be applicable for the initial stool-based test, but would be applicable for the subsequent colonoscopy (because it would be considered a diagnostic testing service given the presence of signs and symptoms of disease based on the result of the initial stool-based test).

[139] *https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21457.*

2. Statutory Authority

Section 1861(s)(2)(R) of the Act includes CRC screening tests in the definition of medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and specifically names the following tests:

- Screening fecal-occult blood test;
- Screening flexible sigmoidoscopy; and
- Screening colonoscopy.

Section 1861(pp)(1)(D) of the Act also authorizes the Secretary to include in the definition of CRC screening tests other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1834(d) of the Act describes limitations for payment of CRC screening tests, including that no payment may be made for CRC screening tests of screening fecal-occult blood test at section 1834(d)(1)(B)(i) of the Act and screening flexible sigmoidoscopy at section 1834(d)(2)(E)(i) of the Act for patients under the age of 50. Section 1834(d) of the Act does not describe a minimum age limit for screening colonoscopy.

Section 1834(n) of the Act, added by section 4105 of the Affordable Care Act, grants the Secretary the authority to modify coverage of certain preventive services identified in section 1861(ddd)(3) of the Act, which in turn cross-references section 1861(ww)(2) of the Act (including CRC screening tests at section 1861(ww)(2)(E) of the Act). The Secretary may modify coverage to the extent that such modification is consistent with the recommendations of the USPSTF, per section 1834(n)(1)(A) of the Act.

3. Regulatory Authority

Our implementing regulations for CRC screening are codified at § 410.37. Similar to section 1834(d) of the Act, § 410.37 describes limitations on coverage and provide that payment may not be made for screening fecal-occult blood tests at § 410.37(c) or screening flexible sigmoidoscopies at § 410.37(e) for individuals under the age of 50. Also similar to section 1834(d) of the Act, § 410.37(g) does not describe a minimum age requirement for screening colonoscopies. Section 410.37 also establishes coverage for screening barium enemas at paragraph (h) and limits coverage to and individual 50 years of age or greater for an individual who is not at high risk of CRC at paragraph (h). Section 410.37(h) does not describe a minimum age limit for coverage of screening barium enemas for individuals who are at high risk of CRC.

4. National Coverage Determination

NCD 210.3 CRC Screening Tests was last revised effective January 19, 2021, when coverage was expanded to include Blood-based Biomarker Tests. NCD 210.3 was previously revised effective October 9, 2014, when coverage was expanded to include The CologuardT—Multi-target Stool DNA (sDNA) Test. Prior to that, NCD 210.3 was revised effective January 1, 2004, when coverage was expanded to include immunoassay-based fecal occult blood test (iFOBT), which can be used as alternative to existing guaiac-based fecal occult blood test (gFOBT). Under NCD 210.3, the Blood-based Biomarker Tests, sDNA test, iFOBT and gFOBT tests all include a limitation of coverage that the patient be at least 50 years of age.

In the NCD 210.3 Final Decision Memo dated January 19, 2021, we noted that multiple commenters provided an alert that a draft USPSTF revised CRC recommendation was circulating and which included a recommendation that CRC screening begin at age 45 instead of 50. The commenters on the draft NCD Decision Memo, in the course of the NCD process, also encouraged CMS to align screening age limitations for all CRC screening tests. At that time, the draft USPSTF recommendation had not been finalized. Therefore, we responded that we are finalizing NCD 210.3 coverage of CRC screening tests with an age range of 50 to 85 years of age. That said, if the draft USPSTF recommendation is finalized and/or other society guidelines are revised, we may reconsider, in consultation with appropriate professional organizations, the appropriate CRC screening tests limitations and address appropriately in an efficient manner.

5. Proposed Revisions

In May 2021, the USPSTF issued a revised recommendation (with a Grade B) that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[140] Accordingly, we propose to exercise our authority under section 1834(n) of the Act to modify coverage of certain CRC screening tests to begin when the individual is age 45 or older. The tests

[140] *https://www.uspreventiveservicetaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

included in the May 2021 USPSTF revised recommendation, including stool-based tests of gFOBT, iFOBT and sDNA, and direct visualization test of flexible sigmoidoscopy. Screening colonoscopy does not have a minimum age requirement under Medicare coverage. We invite public comment on this proposal.

We also propose to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3). While these tests were not recommended in the earlier mentioned May 2021 revised USPSTF recommendation, they are Medicare covered CRC screening tests and would be an important alternative to the stool based and direct visualization tests, especially for individuals with medical complexity and those in rural and underserved communities. We believe that aligning the minimum age requirements for certain Medicare covered CRC screening tests described in our proposal to consistently begin for individuals at age 45 would avoid confusion and reduce barriers for beneficiaries and healthcare professionals. Our proposal reflects our belief that consistent coverage and payment policies will be important in promoting CRC screening, which will result in expanded prevention, early detection and improved health outcomes.

Conforming changes for our proposals to reduce the minimum age for certain CRC screening tests would be made at § 410.37 and NCD 210.3 authorities described earlier. We are not proposing to modify existing conditions of coverage or payment for maximum age limitations and frequency limitations. We also retain the same existing frequency limitations except in the instance of a follow-on screening colonoscopy after a positive result from a non-invasive stool-based CRC screening test described earlier and later in our proposal). We propose to amend § 410.37 paragraph (c)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'', amend paragraph (c)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'', amend paragraph (e)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'', amend paragraph (e)(2) by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'', and amend paragraph (i)(1), by removing the phrase ''individual age 50'' and adding in its place the phrase ''individual age 45''. We also propose to issue formal instructions that would revise the minimum age for the CRC screening tests described in NCD 210.3 from 50 to 45 years.

We consulted with and reviewed recommendations from the following appropriate organizations in our proposal to uniformly reduce the minimum age for certain CRC screening tests from 50 to 45. ACS recommends that people of average risk of CRC start regular screening at age 45 and recommends stool-based tests and visual exam-based tests.[141] The American Society of Colon and Rectal Surgeons (ASCRS) recommends CRC screenings for individuals 45 years of age and older and identifies barium enema as one of multiple screening options.[142] The U.S. Multi-Society Task Force on Colorectal Cancer, which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, also recently revised their recommendation that CRC screening for individuals of average risk of CRC begin at age 45 instead of 50.[143] The Centers for Disease Control and Prevention (CDC) website advises regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early. The CDC website goes on to describe the earlier mentioned May 2021 revised USPSTF recommendations.[144]

We considered the importance of aligning the minimum age requirement for CRC screening across Medicare covered CRC screening tests, as well as private health plans and Medicaid impacted by the May 2021 revised USPSTF recommendation. We believe consistent policy across payers in terms of minimum age limits for CRC screening tests is critical to the public's understanding of evolving CRC screening recommendations. As added by section 2713 of the ACA, 42 U.S.C 300gg–13 requires a that group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements for evidence-based items or services that have in effect a rating of ''A'' or ''B'' by the USPSTF. In addition, we considered that section 1905(a)(13) of the Act, added by section 4106 of the ACA, which expands Medicaid coverage to include screening services that are assigned a grade of A or B by the USPSTF. We believe that expanding coverage for barium enema and blood-based biomarker CRC screening tests to a minimum age of 45, in alignment with the direct visualization and stool-based tests recommended in the May 2021 revised USPSTF recommendation, will allow additional, low burden options and alternatives that may be preferred by some health professionals and patients. While the recommendations from different professional societies and other appropriate organizations include varying detail in terms of specific tests, we understand the growing consensus in the health care community is that the pathology of CRC now requires that broad preventative screening should begin for individuals at age 45 instead of 50. We believe that reducing the minimum age for the Medicare covered CRC screening tests barium enema test (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3) from 50 to 45 years of age, in addition to and in alignment with the direct visualization and stool-based tests described in the 2021 USPSTF recommendation, is appropriate and consistent with our purpose of early detection of colorectal cancer described in § 410.37(a)(1). We received public comment broadly supportive of reducing the minimum age for certain CRC screening tests in both the CY 2022 PFS final rule (86 FR 65179) and in the public comments in response to our Proposed Decisions Memo for NCD 210.3 Screening for Colorectal Cancer—Blood-Based Biomarker Tests (Final Decision Memo dated January 19, 2021). We look forward to further consultation with the public and appropriate organizations through the public comment period for this proposed rule. We invite public comment on this proposal.

We also propose to exercise our authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. In this scenario, we now understand the follow-on screening colonoscopy to be part of a continuum of a complete CRC

[141] *https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html.*

[142] *https://fascrs.org/patients/diseases-and-conditions/frequently-asked-questions-about-colorectal-cancer.*

[143] Gastroenterology. 2022 Jan; 162(1):285–299. doi: 10.1053/j-gastr5o.2021.10.007. Epub 2021 Nov 15.

[144] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

screening and not a separate diagnostic, therapeutic or other procedure. Relatedly, we propose that the frequency limitations described for screening colonoscopy in § 410.37(g) would not apply in the instance of a follow-on screening colonoscopy test after a positive result from a Medicare covered stool-based test. We propose to add new paragraph (k) to§ 410.37 to state that, effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. We aim to avoid disruption to the existing conditions of coverage and payment for CRC screening for this unique scenario and include text noting the frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

We acknowledge that under current Medicare policy, a colonoscopy after a stool-based CRC screening test returns a positive result would be subject to beneficiary cost sharing because it would be considered a diagnostic, therapeutic or other non-screening procedure. Section 410.32(a) describes a diagnostic test as an instance when the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Under current policy, a positive result from the CRC screening stool-based test would be a sign of illness or disease and the subsequent colonoscopy would be for treatment and management of that specific medical problem. We now believe our current policy of CRC screening to not include a follow-on screening colonoscopy after a stool-based test returns a positive result is incomplete and not in full support of our definition of CRC screening test at § 410.37(a)(1) for the purpose of ''early detection of colorectal cancer''.

Our proposal to expand the definition of CRC screening to include a follow-on screening colonoscopy after a stool-based test returns a positive result will include implications for beneficiary cost sharing. Under our proposal, beneficiary cost sharing (coinsurance and deductible) would not be applicable for the stool-based test nor the follow-on colonoscopy screening tests, as described at section 1833(1)(W)(ii) of the Act, as added by section 4104(b) of the Affordable Care Act. When the follow-on screening colonoscopy requires additional procedures furnished in the same clinical encounter, the phased-in Medicare payment percentages for colorectal cancer screening services described in regulation at § 410.152(l) and finalized in the CY 2022 PFS final rule (86 FR 65177 through 65179) will apply. That is, when the follow-on screening colonoscopy includes the removal of tissue or other related services during the same clinical encounter the beneficiary coinsurance will be reduced over time from 15 percent for services furnished during CY 2023 through CY 2026 to 10 percent for services furnished during CY 2027 through 2029 to zero percent beginning in CY 2030 and thereafter.

Our goal is that the patient and their healthcare professional make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and screening colonoscopy tests in terms of invasiveness and burdens to the patient and healthcare system. We recognize there are several advantages to choosing a non-invasive stool-based CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures. It has been reported that a large proportion (46 percent) of screening colonoscopies found no polyps[145] so optimizing use of a non-invasive stool-based screening test as a first step (when determined appropriate by the patient and their healthcare professional) would benefit the patient and also the Medicare program. In many instances, a colonoscopy is not the most appropriate first step in colorectal cancer screening and would represent an unnecessary burden and over-servicing for both the patient and healthcare system. The May 2021 revised USPSTF recommendation reads, ''stool-based screening requires persons to collect samples directly from their feces, which may be unpleasant for some, but the test is quick and noninvasive and can be done at home (the sample is mailed to the laboratory for testing), and no bowel preparation is needed to perform the screening test.'' [146] The May 2021 revised USPSTF recommendation goes on to described that direct visualization CRC screening tests such as screening colonoscopy and screening flexible sigmoidoscopy must be performed in a clinical setting rather than home and require bowel preparation prior to the test. In addition, sedation or anesthesia is usually used during screening colonoscopy and the patient requires additional recovery time and assistance with transportation home.

We have heard from interested parties that CMS should consider a complete CRC screening to include a follow-on screening colonoscopy when a non-invasive stool-based test returns a positive result. We consulted with and reviewed recommendations from a number of professional societies in developing this proposal, including supportive letters and communications with representatives from American Gastroenterological Association, American Cancer Society Cancer Action Network, and Fight Colorectal Cancer. Our proposal regarding a new understanding of a complete CRC screening aligns with a policy recommendation from the National Colorectal Cancer Roundtable, which was ''established by the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC) in 1997, is a national coalition of public organizations, private organizations, voluntary organizations, and invited individuals.'' [147] Our proposal also aligns to a 2018 CRC screening guideline update from the American Cancer Society, which reads ''Implementation of the screening options included in this guideline is premised on the requirement that the appropriate follow-up to a positive (noncolonoscopic) test is a timely colonoscopy. The follow-up colonoscopy should not be considered a ''diagnostic'' colonoscopy but, rather, an integral part of the screening process, which is not complete until the colonoscopy is performed. The information provided to patients to facilitate a choice among tests must include the importance of follow-up of a positive (noncolonoscopic) test with colonoscopy. Repeating a positive stool-based test to determine whether to proceed to colonoscopy is not an appropriate screening strategy.'' [148]

We also considered the May 2021 revised USPSTF recommendation,

[145] Lieberman DA, Weiss DG, Bond JH, Ahnen DJ, Garewal H, Chejfec G. Use of colonoscopy to screen asymptomatic adults for colorectal cancer. Veteran sAffairs Cooperative Study Group 380. N Engl J Med. 2000 Jul 20;343(3):162–8. doi:10.1056/NEJM200007203430301. Erratum in: N Engl J Med 2000 Oct 19;343(16):1204. PMID: 10900274.

[146] *https://www.uspreventiveservicetask.org//uspstf/recommendation/colorectal-cancer-screening.*

[147] *https://nccrt.org/about/.*

[148] *https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21457.*

which includes the statement ''When stool-based tests reveal abnormal results, follow-up with colonoscopy is needed for further evaluation . . . Positive results on stool-based screening tests require follow-up colonoscopy for the screening benefits to be achieved.''[149] We also note that the U.S. Departments of Labor, Health and Human Services (HHS), and the Treasury issued a Frequently Asked Questions guidance on January 10, 2022 that reads, ''A [non-grandfathered group health] plan or [health insurance issuers offering non-grandfathered group or individual health insurance coverage] must cover and may not impose cost sharing with respect to a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals described in the USPSTF recommendation. As stated in the May 18, 2021 USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.[150] The follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization screening test is therefore required to be covered without cost sharing in accordance with the requirements of PHS Act section 2713 and its implementing regulations.'' [151]

We believe that our proposal to update our regulations to align to our new understanding of a complete CRC screening will address the beneficiary cost sharing barrier that currently exists for a subsequent colonoscopy after an initial stool-based test returns a positive result, would allow more options for healthcare professionals and patients, would help optimize non-invasive CRC screening test use, and improve health outcomes for Medicare beneficiaries. We received public comment supportive of the policy described in our proposal in both the CY 2022 PFS final rule (86 FR 65179) and in public comments to our Proposed Decision Memo for the NCD 210.3 Screening for Colorectal Cancer—Blood-Based Biomarker Tests (Final Decision Memo dated January 19, 2021).[152] We look forward to further consultation with the public and appropriate organizations through the public comment period for this proposed rule. We invite public comment on this proposal.

The scope of our proposals is limited to CRC screening tests and do not address the coverage or payment status of other screening services or tests recommended by the USPSTF or covered by Medicare.

6. Summary

In summary, we propose to exercise our authority in section 1834(n) and 1861(pp)(1)(D) of the Act to expand CRC screening coverage by reducing the minimum age for CRC screening tests from 50 to 45 years of age for certain Medicare covered CRC screening tests that currently include a minimum age of 50 as a limitation of payment or coverage. A screening colonoscopy would continue to not have a minimum age limitation under our proposal. We also propose to exercise our authority in section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening to include a follow-on screening colonoscopy after a non-invasive stool-based test returns a positive result. We believe our proposals will expand access to quality care and improve health outcomes for patients through prevention, early detection, more effective treatment and reduced mortality.

E. Removal of Selected National Coverage Determinations

CMS periodically identifies and proposes to remove National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries. Clinical science and technology evolve, and items and services that were once considered state-of-the-art or cutting edge and experimental may later be established as reasonable and necessary for Medicare beneficiaries or replaced by more beneficial technologies or clinical paradigms.

Since the CY 2021 PFS final rule (85 FR 84472), we have used notice and comment rulemaking to obtain public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Using rulemaking under section 1871(a)(2) of the Act allows for efficiencies in timing and process to consider removal of NCDs, as compared to the public comment process established in section 1862(l) of the Act, to be used in making and reconsidering individual NCDs through the National Coverage Analysis process.

Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically, nationally covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). On the other hand, removing an NCD that bars coverage for an item or service under title XVIII of the Act (that is, national noncoverage NCD), allows MACs to cover the item or service if the MAC determines that such action is appropriate under the statute. Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research, which produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

In the CY 2021 PFS final rule, we did not establish an exclusive list of criteria that we would use for identifying and evaluating NCDs for removal. Instead, based on recommendations in public comments, and to be more flexible and nimble, we added considerations to the six factors established in 2013 to guide our decision making process. In addition to the six factors listed below, we also consider the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology development since the last determination, and availability and quality of clinical evidence and information to support removal of an NCD. We would consider proposing the removal of an NCD if any of the following factors are present:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.

[149] *https://www.uspreventiveservicetaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[150] The quoted text from the January 10, 2022 Frequently Asked Questions guidance includes a footnote to this portion of the text that reads, ''In addition, in its 'Supporting Evidence' section, the USPSTF Full Recommendation Statement states: 'Several comments requested that colonoscopy to follow up an abnormal noncolonoscoy screening test result be considered part of screening. The USPSTF recognizes that the benefits of screening can only be fully achieved when follow-up of abnormal screening test results is performed. The USPSTF added language to the Practice Considerations section to clarify this.' ''

[151] *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.*

[152] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=299.*

• The NCD has been superseded by subsequent Medicare policy.

• The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act.

• The benefit category determination is no longer consistent with a category in the statute.

When we evaluate particular NCDs for removal, we review and consider information gathered from interested parties, particularly literature or evidence that supports a change in coverage, the Medicare claims data for those items and services, and other factors such as whether there may be documentation requirements within the NCD that are outdated or create a barrier to coverage. The rulemaking process provides an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

In addition to conducting an internal review to identify appropriate NCDs for removal, we receive removal requests from a variety of external interested parties, such as medical specialty societies, device manufacturers, beneficiaries, physicians and providers, and other interested individuals with many of those requests submitted as public comments to the PFS proposed rules. Additionally, sometimes topics are brought to our attention by the MAC medical directors.

The following outlines the NCD proposed for removal and provides a summary of the rationale for removal. The current NCD below is available in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961*.

1. NCD 160.22 Ambulatory EEG Monitoring (06/12/1984)

• *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* Ambulatory, or prolonged electroencephalographic (EEG) monitoring is a diagnostic test that continuously records the brain's electrical activity during a patient's routine daily activities and sleep. Ambulatory EEG monitoring may be used to diagnose seizure disorders and metabolic, infectious, or inflammatory disorders that affect the brain's activity, particularly when a resting/routine EEG is not conclusive. The NCD currently defines ambulatory EEG monitoring as 24-hour EEG monitoring and provides coverage for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG. The NCD also provides that ambulatory EEG can be utilized in the differential diagnosis of syncope and transient ischemic attacks if not elucidated by conventional studies. Additionally, the NCD states that ambulatory EEG ''should always be preceded by a resting EEG''. External interested parties recommended removal of this NCD. The NCD contains outdated language that is inconsistent with, and contrary to current standards of care. For example, the NCD contains references to cassette tapes. This outmoded technology has been supplanted with more modern techniques that are more accurate and convenient for monitoring. The document uses the word ''ambulatory,'' implying certain sites of service whereas this diagnostic test is not site specific. The NCD makes mention of a 24-hour duration of monitoring. However, the more recent coding structures permit monitoring in increments including 36–60 hours, 60–84 hours, and >84 hours. Additionally, interested parties stated that the language ''should always be preceded by a resting EEG'' could potentially create waste and a burden. Interested parties indicated that in some clinical scenarios, a ''resting/routine'' EEG is unlikely to adequately detect seizure or other brain activity that would be useful for diagnostic purposes, but would be detected by prolonged EEG testing. Removing the outdated NCD will allow MACs to update guidance for this established diagnostic test.

In summary, we solicit comment on the proposal to remove NCD 160.22 Ambulatory EEG Monitoring. We use the public comments to help inform our decision to take one of three actions on the NCD proposed for removal:

• Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.

• Retain the current policy as an NCD.

• Reconsider the NCD by opening a National Coverage Analysis. Comments suggesting that the NCD should be revised, rather than eliminated, should include new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a change in national coverage.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. In the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone. We also revised the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met (86 FR 65342). We are continuing to monitor Medicare enrollment by OTPs and utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care, as well as monitoring for fraud, waste, and abuse. For CY 2023, we are proposing several modifications to the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Methadone Pricing

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy in

§ 410.67(d)(2)(i) under which the payment for the drug component of episodes of care would be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. Under the policy finalized at § 410.67(d)(2)(i)(B), for oral medications, if average sales price (ASP) data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart J and voluntarily-submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. Using this established method, we determined that the payment amount for methadone furnished by OTPs during an episode of care in CY 2021 was $37.38,[153] which was 100 percent of ASP, as determined based on voluntarily-submitted ASP data for methadone.

In early September 2021, while gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to the CY 2021 rate, from $37.38 to $17.64.[154] This reduction was due to inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. The ASP is volume-weighted; however, ASP reporting is not required for oral methadone and only a small subset of methadone manufacturers voluntarily submit ASP data. In September 2021, of the nearly 50 available NDCs for oral methadone preparations with available pricing in the Red Book® compendia, voluntarily-submitted ASP data was available for only three of these NDCs. Pricing for oral methadone is distinct from most other drug pricing based on ASP because oral methadone is not separately payable as a drug or biological under Medicare Part B, and manufacturers are not subject to ASP reporting requirements under section 1927(b)(3)(A)(iii) of the Act for those NDCs. Additionally, we do not have utilization data on the different forms of methadone that can be dispensed or administered at OTPs. That is, we do not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally. When we researched OTP practice patterns as we were preparing to implement the new benefit for OUD treatment services furnished by OTPs, we received anecdotal reports that several OTPs used the oral concentrate exclusively.

For these reasons, while performing our annual ratesetting exercise for CY 2022, we had concerns as to whether the ASP data available to us at that time, which reflected voluntarily reported data from only a very small subset of methadone manufacturers, was representative of utilization of the two forms of oral methadone by the Medicare beneficiaries receiving OUD treatment services in OTPs. Additionally, given reports regarding the effects of the public health emergency (PHE) for COVID–19 on individuals with substance use disorders (SUDs), including OUD, and the questions we had related to whether the ASP data we had for methadone was reflective of OTP utilization due to the distinct nature of methadone pricing, as described above, we believed it was in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue, seek input from the OTP community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. We noted that section 1834(w)(2) of the Act allows for flexibility to consider the scope of services furnished, the characteristics of the individuals receiving services, and such other factors as the Secretary determines appropriate, in determining the rates paid to OTPs under Medicare.

Therefore, we issued the ''Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception'' interim final rule with comment period (IFC) (hereafter referred to as ''Methadone IFC''), which appeared in the November 19, 2021 **Federal Register** (86 FR 66031 through 66036). In the Methadone IFC, we established a limited exception to the methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the $37.38 payment amount that was determined for CY 2021. We also revised the regulation at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception for CY 2022 and to make a conforming change to the reference to 42 CFR part 414, subpart J.

Under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) was maintained at the CY 2021 rate of $37.38 for the duration of CY 2022. We also applied the annual update to the non-drug component of HCPCS G2067 for CY 2022 as required under § 410.67(d)(4)(iii). We stated that we believed maintaining the payment amount for methadone at the CY 2021 rate during CY 2022 would allow time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for CY 2023 (86 FR 66033). We solicited comments on this exception to the payment methodology for the drug component of an episode of care in order to maintain the payment rate for methadone at the CY 2021 payment amount during CY 2022. In addition, we sought comments on OTP utilization patterns for methadone, particularly the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic. We also stated that we would consider the comments received in determining how best to determine the payment rate for methadone in CY 2023, including whether we should propose changes to the structure of OTP coding and payment in order to account for differences in pricing and utilization of the different formulations of methadone.

We received several comments in response to the Methadone IFC from medical associations, national associations representing OTPs, and

[153] *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.*

[154] The TRICARE rate for the drug portion of its weekly bundled payment for methadone treatment is $24.04 for 2022, which would also have been a decrease from the CY 2021 payment rate under Medicare and could not be used to set the Medicare payment rate for methadone in CY 2022 under § 410.67(d)(2)(i)(B) because ASP data was available for methadone.

individual commenters that expressed strong support for stabilizing the payment rate for methadone. One commenter stated cutting reimbursements to providers who specialize in treatment for OUD in the middle of an OUD epidemic that has been exacerbated by the COVID–19 pandemic could have harmful consequences for beneficiaries and cited that the HHS Office of Inspector General (OIG) expressed concern that Medicare beneficiaries face challenges accessing OUD treatment. The commenter also stated that if Medicare reimbursements for methadone fall well below OTPs' costs of acquiring and administering the medication, OTPs may have no choice but to prescribe a much more expensive medication (buprenorphine or naloxone) as part of medication-assisted treatment (MAT)/Medications for Opioid Use Disorder (MOUD), which would result in higher costs for the Medicare program and taxpayers, while not necessarily improving care. For example, methadone is often more ideal for severe dependence or if there is a high risk of divergence, while buprenorphine may be more advantageous for mild to moderate dependence and when extensive supervision by a practitioner is not needed.[155] Another commenter stated that it is possible that freezing the payment rate for methadone at the current level could still result in some negative outcomes, as supply chain and logistics issues have generally resulted in increased prices across the country such that a payment rate increase may be necessary, but thought that freezing the rate at the current level was a prudent solution for 2022. A commenter representing a large number of OTPs across the country stated that OTPs rarely dispense methadone tablets and instead administer the oral concentrate formulation. This commenter stated that methadone oral concentrate is more expensive to acquire and administer than the tablet form, but that it has been shown to lead to better clinical outcomes for their patients, which is why it is their doctors' formulation of choice. This commenter went on to state that the existing methodology to calculate the payment rate for the drug component of the methadone weekly bundle does not accurately capture the extra costs associated with administration of the oral concentrate, explaining that oral concentrate formulations require careful measurement in addition to maintaining electric pumps and updating computer software. The commenter also noted that it is expensive to employ the necessary nursing staff, and stated that a number of States require full-time pharmacists for the dispensing and administration of medication. Another commenter noted that the National Association of State Alcohol and Drug Abuse Directors (NASADAD), in conjunction with the State Opioid Treatment Authorities (SOTAs), conducted a survey that was distributed to the 1,800 OTPs throughout the United States. As of December 31, 2021, NASADAD and the SOTAs had collected data from 1,550 OTPs. These data include the number of patients being treated at OTPs as of January 1, 2021, including the number of patients using one of the three FDA-approved medications to treat opioid use disorder (methadone, buprenorphine, and extended-release naltrexone) and the specific forms of the medication being used.

We appreciate the feedback received in response to the Methadone IFC. We agree with commenters that decreasing the payment amount for methadone in the middle of an OUD epidemic that has been exacerbated by the COVID–19 pandemic could have harmful consequences for beneficiaries as we discussed in the Methadone IFC (86 FR 66032). We are also looking forward to seeing the results of the survey initiated by NASADAD and the SOTA, so that we can better understand the utilization of methadone tablets and oral concentrate in OTPs.

In light of the comments received, we have considered how best to maintain access to treatment with methadone in the OTP setting for Medicare beneficiaries. We considered splitting the methadone bundled payment code into two codes—one for oral concentrate and one for the tablet. This would allow us to track Medicare utilization of each formulation. However, because of the inconsistency in available ASP data for orally administered methadone due to the fact that manufacturer reporting of sales data for these dosage forms of methadone is voluntary, (that is, orally administered methadone is not a drug that falls under the ASP reporting requirements under sections 1927(b)(3)(A)(iii) or 1847A(f)(2)(A) of the Act), we do not believe that voluntary reporting of ASP data for either form of orally administered methadone (oral concentrate or tablet) currently provides a reliable source for pricing the methadone codes. For example, for the first quarter of 2022, there was no ASP data reported for orally administered methadone. Under the policy at § 410.67(d)(2)(i)(B)(*1*), when ASP data are not available for methadone, we would base the payment amount for methadone on the TRICARE rate. We found that the applicable TRICARE payment amount for methadone for CY 2022 would be $24.04. Using the TRICARE payment amount for methadone for CY 2023 would result in a decrease of $13.34 compared to the rate that applied in CY 2021 and CY 2022. We believe that this decrease would be problematic for all of the reasons that we expressed in the Methadone IFC (86 FR 66034 through 66035). For these reasons, we believe that it is appropriate to propose an alternate methodology for pricing the drug component of the methadone bundle and the methadone add-on code in order to maintain payment stability, and therefore, maintain appropriate access to OUD treatment services furnished at OTPs for Medicare beneficiaries.

In the CY 2020 PFS final rule (84 FR 62667), we discussed the methods we had considered for providing an update each year to the drug component of the OTP bundled payment rates. We stated that we considered annually updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the Producer Price Index (PPI) for chemicals and allied products, analgesics (WPU06380202). We explained that the PPI for chemicals and allied products, analgesics is a subset of the PPI produced by the Bureau of Labor Statistics (BLS). We solicited comments on this approach but did not receive any comments. Ultimately, we decided against proposing to update the pricing of the drug component of the OUD treatment services payment rate via an established update factor, such as the PPI, in favor of an update using the most recently available ASP data at the time of ratesetting for the applicable calendar year. We explained that we believed an ASP-based approach would update the pricing of the drug component of the OUD treatment services payment rate in a manner that would be more consistent with other Medicare payments under Part B.

Because we do not believe that ASP data can provide an appropriate reflection of the changes in methadone costs for OTPs until such a time that more complete and reliable ASP data are available for methadone, we are reconsidering the use of the PPI to update the payment rate for methadone. According to the U.S. BLS,[156] the PPI program measures the average change over time in the selling prices received

[155] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3271614/.*

[156] *https://www.bls.gov/ppi/.*

by domestic producers for their output. The application of an annual adjustment factor would be consistent with Medicare payment policy in other areas, such as the outpatient prospective payment system, which updates the conversion factor used to set payment rates under that payment system by applying the outpatient department fee schedule increase factor, which is equal to the percentage change in the hospital inpatient market basket (86 FR 63498 through 63500). The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase to provide inpatient care.

The PPI for Pharmaceuticals for Human Use (Prescription) (WPUSI07003) reflects price changes associated with the average mix of all pharmaceuticals in the overall economy and is both publicly available and regularly published. We believe that this PPI would be an appropriate factor to adjust the payment rate for methadone to reflect the changes in methadone costs for OTPs over time. Methadone is an established drug in the drug supply chain, and we believe that an overall price trend that incorporates price changes for prescription pharmaceuticals would provide an appropriate update to reflect any increase in the costs incurred by OTPs in furnishing methadone during episodes of care.

Accordingly, for CY 2023 and subsequent years, we are proposing to revise our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. Under this proposal, we would base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription). We propose to update the methadone payment amount for CY 2023 based on the projected increase in the PPI for Pharmaceuticals for Human Use (Prescription) to reflect the forecasted price growth for prescription drugs for the 2-year period from CY 2021 to 2022 and from CY 2022 to 2023. Because we froze the payment amount for methadone at the 2021 amount for CY 2022, we propose to account for the inflation for both CY 2022 and CY 2023 in setting the payment rate for CY 2023. Based on the 2022 Q1 forecast from IHS Global Inc. (IGI) the proposed CY 2023 methadone payment amount would be $39.29, which is the CY 2022 payment amount of $37.38 increased by a projected 5.1 percent growth in the PPI for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023 ($37.38 * 1.051 = $39.29). IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast various price proxies used in the CMS market baskets. Additionally, we are proposing that if more recent data become subsequently available (for example, a more recent estimate of the PPI), we would use such data in the final rule to determine the final CY 2023 methadone payment amount. For subsequent years, we are proposing to continue to update this rate annually using the PPI for Pharmaceuticals for Human Use (Prescription). We note that under this proposal, we would continue to monitor methadone pricing in order to determine whether we may need to propose additional changes to this methodology through future rulemaking to account for any significant changes in the acquisition costs for methadone. We may also revisit this policy in the event that new or more reliable data on methadone pricing become available. We also solicit public comment on other potential data sources that could be used to estimate an OTP's cost for acquiring methadone.

Accordingly, we are proposing to revise the regulation at § 410.67(d)(2)(i)(B)(2) to state that for CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount for methadone in CY 2021 as determined under § 410.67(d)(2)(i)(B)(1) and updated by the PPI for Pharmaceuticals for Human Use (Prescription). Under this proposal, the TRICARE rate would no longer be an alternative pricing methodology for methadone. As part of this proposal, we would also correct an inadvertent error in the text of the current regulation at § 410.67(d)(2)(i)(B)(2), which includes an inaccurate cross-reference to paragraph (d)(2)(i)(B)(1).

3. Proposed Changes to the Rate for Individual Therapy in the Bundled Rate

In the CY 2020 PFS final rule (84 FR 62658), we finalized a payment rate for the non-drug component of the bundled payment for episodes of care that was calculated using a building block methodology in which we took the sum of rates for similar services paid under the PFS. The payment rate for individual therapy included in the non-drug component of the bundled payment for an episode of care is currently based on a crosswalk to CPT code 90832, which describes 30 minutes of psychotherapy.

In its December 2021 report,[157] titled ''Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder,'' OIG indicated that approximately one million Medicare beneficiaries were diagnosed with OUD in 2020, but less than 16 percent of those beneficiaries received medication to treat OUD (in any setting), raising concerns that beneficiaries face challenges accessing treatment. In this report, OIG also stated that in 2020, less than 4 percent of Medicare beneficiaries with OUD received treatment from OTPs. We note that 2020 was the first year of the Medicare OTP benefit and that OTPs had to submit applications for enrollment with Medicare and have those applications approved prior to billing services to Medicare. As a result, we expect these numbers to improve in future years. However, CMS has been working to identify and track drivers of disparities in the treatment of OUD.

Additionally, we have received feedback from interested parties, including associations and groups that represent OTPs, indicating that the current rate for individual therapy provided as part of the weekly bundle may not accurately reflect the resource costs involved with furnishing this service in the OTP setting and that for the first several months of treatment, patients typically receive weekly 50-minute individual therapy sessions. Now that we have 2 years of utilization data, we have reviewed how we implemented the OTP benefit to determine whether refinements to the bundled rate may be warranted to reflect more accurately the level of services furnished by OTPs.

We believe that the severity of needs of the patient population diagnosed with OUD and receiving services in the OTP setting is generally greater than that of patients receiving 30-minute psychotherapy services paid under the PFS. For example, co-occurring substance use and mental health disorders are common among adults with OUD.[158] Individuals with co-occurring SUD and mental health disorders likely have complex treatment needs and may have different patterns of treatment than individuals diagnosed with a single condition.[159] During the first few months of treatment at an OTP, patients generally receive care at the OTP on a daily basis. Based on the generally greater severity of needs of the patient population receiving services at

[157] *https://oig.hhs.gov/oei/reports/OEI-02-20-00390.pdf.*

[158] *https://www.sciencedirect.com/science/article/pii/S0376871618305209.*

[159] *https://www.sciencedirect.com/science/article/pii/S0740547218304781.*

OTPs compared to patients receiving psychotherapy services billed under CPT code 90382 and paid under the PFS, and therefore, the greater intensity of the work, we believe it is appropriate to re-visit the rate for individual therapy that is included in the non-drug component of the weekly episodes of care.

Accordingly, we are proposing to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 (Psychotherapy, 45 minutes with patient), instead of a crosswalk to CPT code 90832 (Psychotherapy, 30 minutes with patient), as is our current policy. We believe CPT code 90834 most closely corresponds to a 50-minute therapy session, which interested parties have indicated is the typical amount of therapy received by patients in the first few months of treatment at an OTP. In the CY 2020 PFS final rule (84 FR 62658), we stated that we based the rate for individual therapy in the bundled payment on the 2019 non-facility payment rate for CPT code 90832, which was $68.47. Therefore, in order to change the rate for individual therapy, we are proposing to substitute the 2019 rate for CPT code 90832 included in the non-drug component of each of the bundled payments for an episode of care with the 2019 PFS non-facility payment rate for CPT code 90834, which was $91.18, to determine an adjusted payment rate for CY 2020 for the non-drug component of each applicable HCPCS code. As described in § 410.67(d)(4)(iii), we would then apply the Medicare Economic Index (MEI) updates for 2021, 2022, and 2023 to these adjusted payment rates to determine the CY 2023 payment amounts for the non-drug component of the bundled payments for an episode of care. In section II.M. of this proposed rule, we are proposing to rebase and revise the MEI from a 2006-base year to a 2017-base year. The MEI for CY 2023 is currently projected to be 3.8 percent based on the proposed 2017-based MEI, and is based on the most current forecast of the percentage increase of the proposed 2017-based MEI for the second quarter of 2022 (4.2 percent), and the most recent estimate of the historical productivity adjustment for calendar year 2021 (0.4 percent). The MEI for CY 2023 will be revised for the final rule based on the historical data through the second quarter 2022 and the most recently available total factor productivity data.

We note that in the CY 2020 PFS final rule (84 FR 62644), we also finalized an adjustment to the bundled payment rates through the use of an add-on code to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan. This adjustment is described by HCPCS code G2080 (Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.). We are not proposing any changes to HCPCS code G2080. We believe that our proposal to update the crosswalk we use to calculate the individual therapy portion of the non-drug component of the bundled payment to reflect 45 minutes of psychotherapy does not duplicate the add-on code for additional counseling. Rather, we believe that our proposal to update the crosswalk for individual therapy will ensure that the payment for the non-drug component of the bundled payment is more representative of the typical case in the OTP setting and better reflects the resource costs involved in furnishing this service in the OTP setting compared to the current crosswalk.

Accordingly, we are proposing to revise the regulation text at § 410.67(d)(2) to adjust the payment for the non-drug component of the bundled payment for an episode of care to reflect 45 minutes of psychotherapy beginning in CY 2023. We welcome comments on this proposal.

4. Mobile Components Operated by OTPs

Effective July 28, 2021, the Drug Enforcement Administration (DEA) issued a final rule (86 FR 33861) that authorized OTPs to add a ''mobile component'' to their existing registration, which eliminated a requirement for mobile medication units of OTPs to have a separate registration. Additionally, we note that SAMHSA has issued guidance to OTP Directors, State Opioid Treatment Authorities (SOTAs), and State Directors that revised and superseded related portions of SAMHSA's 2015 Federal Guidelines for OTPs by clarifying the range of services that can be provided by mobile units.[160]

In light of the new SAMHSA guidance, we wish to clarify that services furnished via OTP mobile units will be considered for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. We believe that allowing OTPs to bill Medicare for services furnished via mobile units is an opportunity to expand access to medications for treatment of OUD for Medicare beneficiaries by extending the reach of OTPs, particularly in remote or underserved areas. Because OTPs receive a bundled payment, we believe it would be appropriate to apply locality adjustments for services furnished via mobile units as if the service were furnished at the OTP registered with DEA and certified by SAMHSA. We anticipate that for beneficiaries receiving OUD treatment services from a mobile unit, some services included in the bundle for a given week may still be provided at the OTP, while some may be furnished via the mobile unit, which would make it difficult to determine which geographic locality adjustment to apply to the weekly bundle if the OTP and the location served by the mobile unit are subject to different geographic locality adjustments. Additionally, when services are furnished from a mobile unit, the OTP still incurs the cost of rent, staffing, supplies, etc. at the location of the OTP; therefore, we believe it is appropriate to apply the geographic locality adjustment as if the service were furnished at the OTP. Accordingly, we are proposing to amend the regulation at § 410.67(d)(4)(ii) to clarify that for purposes of the geographic adjustment OUD treatment services furnished via an OTP mobile unit will be treated as if the services were furnished at the physical location of the OTP registered with DEA and certified by SAMHSA. As stated in the CY 2020 PFS final rule, because HCPCS codes G2067–G2075 cover episodes of care of 7 contiguous days, OTPs should not bill any of these codes for the same beneficiary more than once per 7 contiguous day period, with limited exceptions (84 FR 62649), and we are not proposing any changes to this policy, regardless of the location(s) at which the services are provided. As noted previously, we will continue monitoring the benefit for OUD treatment services furnished by OTPs, including services furnished by mobile units, for fraud, waste, and abuse, and will use existing administrative authorities to take necessary action, as appropriate.

[160] *https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf.*

5. Flexibilities for OTPs to Use Telecommunications for Initiation of Treatment With Buprenorphine

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the PHE for COVID–19 and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the IFC entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised § 410.67(b)(3) and (4) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when the beneficiary cannot access or does not consent to the use of audio and video.

In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise § 410.67(b)(7) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met, on a permanent basis. However, the flexibility for OTPs to furnish periodic assessments via audio-only communication is limited to the duration of the PHE for COVID–19. There are currently no flexibilities under Medicare for OTPs to furnish the intake add-on code via communication technology.

SAMHSA regulations under 42 CFR 8.12(f)(2) require a complete physical evaluation before a patient begins treatment at an OTP. However, during the PHE, DEA and SAMHSA have allowed OTPs to initiate treatment with buprenorphine via audio-video and audio-only communication without first conducting an in-person evaluation.[161] According to guidance issued by SAMHSA [162] regarding the treatment of OUD during the PHE, SAMHSA made the decision to exercise its authority to exempt OTPs from the requirement to perform an in-person physical evaluation (under 42 CFR 8.12(f)(2)) for any patient who will be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth. This exemption applies exclusively to OTP patients treated with buprenorphine and does not apply to new patients treated with methadone. This exemption will continue only for the duration of the declared PHE for COVID–19 unless regulations are issued making this flexibility permanent.

For services paid under the PFS, Medicare telehealth services fall under the authority of section 1834(m) of the Act, which generally limits payment for telehealth services to those furnished to patients located in specified types of medical care settings in mostly rural locations. The codes describing new patient office/outpatient visits (CPT codes 99202 through 99205) are on the Medicare Telehealth list. As discussed in the CY 2019 PFS final rule (83 FR 59496), section 2001(a) of the SUPPORT Act (Pub. L. 115–271, October 24, 2018) amended section 1834(m) of the Act, adding a new paragraph (7) that removed the geographic limitations for telehealth services furnished on or after July 1, 2019, to individuals with a diagnosed SUD for the purpose of treating the SUD or a co-occurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. In addition, as discussed in the CY 2022 PFS final rule (86 FR 65055), section 123 of the Consolidated Appropriations Act, 2021 (CAA 2021) (Pub. L. 116–260, December 27, 2020) modified the circumstances under which Medicare makes payment under the PFS for mental health services furnished via telehealth following the PHE. Specifically, it removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. In addition to the flexibilities authorized by section 2001(a) of the SUPPORT Act and section 123 of the CAA 2021, in the CY 2022 PFS final rule (86 FR 65055), for services for the diagnosis, evaluation or treatment of mental health conditions, including SUDs, CMS revised the regulatory definition of an ''interactive telecommunications system'' to permit the use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home.

Given these flexibilities for the treatment, diagnosis, or evaluation of mental health disorders, including SUDs, under the PFS, we are proposing to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We are also proposing to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of

[161] *https://www.deadiversion.usdoj.gov/coronavirus.html.*

[162] *https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.*

or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. We note under this proposal, the initiation of treatment with buprenorphine using telecommunications technology would be considered an intake activity for purposes of § 410.67(b)(6) only to the extent that the use of such telecommunications technology is permitted under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished.

Accordingly, we are proposing to revise the regulation at § 410.67(b)(6) to state that services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where two-way audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine can be furnished using audio-only telephone calls if all other applicable requirements are met.

Finally, we are seeking comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As of January 1, 2022, over 11 million people with Medicare receive care from one of the 528,966 health care providers in the 483 accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (Shared Savings Program), the largest value-based purchasing program in the country.[163] Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending. The proposed changes to the Shared Savings Program described in this section of this proposed rule, and the topics on which we seek comment, are intended to advance Medicare's value-based care strategy of growth, alignment, and equity, with many proposals overlapping these categories.

The Shared Savings Program offers different participation options (tracks) that allow ACOs to assume various levels of risk. The BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings and shared losses models[164] within a single 5-year agreement period.[165] ACOs that enter the ENHANCED track accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards. For the performance year beginning on January 1, 2022, 59 percent of Shared Savings Program ACOs are under two-sided models. Historically, we have observed that ACOs in performance-based risk tracks have better financial performance than ACOs in shared savings only tracks and that low revenue ACOs (which may tend to be small, physician only ACOs) have better financial performance than high revenue ACOs (whose composition likely includes institutional providers, particularly hospitals and health systems).[166] We have also observed that the highest earning ACOs had a higher proportion of beneficiaries that were members of racial and ethnic minority communities and included a greater proportion of ESRD, disabled, and aged/dual eligible Medicare and Medicaid beneficiaries than the lowest earning ACOs.

Through the changes we are proposing in this proposed rule, we also seek to reverse certain recent trends[167] [168] in the Shared Savings Program: in recent years growth in the number of beneficiaries assigned to ACOs has plateaued; higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks; and access to ACOs appears inequitable as shown by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO than their Non-Hispanic White counterparts.

Several of the proposals we are making in this proposed rule are expected to advance equity within the Shared Savings Program. Based on feedback from health care providers treating underserved populations that they require upfront capital to make the necessary investments to succeed in accountable care and may also need additional time under a one-sided model before transitioning to performance-based risk, we are proposing to provide advance shared savings payments to low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program (that is, not a renewing ACO or a re-entering ACO), and that serve underserved populations. These advance investment payments (AIPs) would increase when more beneficiaries who are dually eligible for Medicare and Medicaid or who live in areas with high deprivation (measured by the area deprivation index (ADI)), or both, are assigned to the ACO. Subject to certain limitations, these funds would be available to address the social needs of people with Medicare, as well as health care provider staffing and infrastructure. We are also proposing other modifications to certain existing policies under the Shared Savings Program to support organizations new to accountable care by providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign

[163] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2022, available at *https://www.cms.gov/sites/default/files/2022-01/2022_Shared_Savings_Program_Fast_Facts.pdf.*

[164] As explained in earlier rulemaking, we have tended to use the terms ''two-sided model'' and ''performance-based risk'' interchangeably, considering them to be synonymous when describing payment models offered under the Shared Savings Program and Medicare ACO initiatives more broadly (83 FR 67827).

[165] As explained in earlier rulemaking (for example, 83 FR 67844), the BASIC track's glide path includes 5 levels: a one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E).

[166] See for example, 83 FR 67820.

[167] Refer to the ''Shared Savings Program Fast Facts—As of January 1, 2022'' available at *https://www.cms.gov/sites/default/files/2022-01/2022_Shared_Savings_Program_Fast_Facts.pdf.*

[168] Refer to the ''Performance Year Financial and Quality Results'' Public Use Files available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.*

their care processes to be successful under risk arrangements. We are proposing a health equity adjustment that would upwardly adjust ACOs' quality performance scores to continue encouraging high ACO quality performance, transition ACOs to all-payer eCQMs/MIPS CQMs, and support those ACOs serving a high proportion of underserved beneficiaries while also encouraging all ACOs to treat underserved populations. Finally, we are proposing certain changes to our benchmarking methodologies that are designed to encourage participation by health care providers who care for populations that include a high percentage of beneficiaries with high clinical risk factors and beneficiaries dually eligible for Medicare and Medicaid.

Many of these proposals are the result of our efforts to align policies under the Shared Savings Program and under the Innovation Center's ACO models. For example, the proposed AIPs are derived from learnings from the ACO Investment Model (AIM), an Innovation Center model that tested the effects of making advanced payments to certain ACOs participating in the Shared Savings Program. This proposal to incorporate AIPs into the Shared Savings Program payment methodology is an example of how our larger ACO strategy of having the Innovation Center test new payment and service delivery models on the Shared Savings Program ''chassis'' can better harmonize policies across Medicare ACO initiatives and enable us to scale any findings.

The Innovation Center recently announced the elimination of the ACO Track of the Community Health and Rural Transformation (CHART) Model, which would have provided advance shared savings payments to new rural ACOs participating in SSP, similar to AIM. We believe the proposal to incorporate AIPs into the Shared Savings Program will make the Shared Savings Program attractive to organizations that were previously considering participation in the ACO Track of the Community Health and Rural Transformation (CHART) Model. The CHART Model ACO Track specifically targeted ACOs whose providers and suppliers were located in rural areas. We believe the proposed methodology to determine payments based upon a beneficiary's risk factors-based score will allow for greater reach to ACOs operating in under-resourced communities and encourage providers and suppliers in rural areas to form ACOs.

As we seek to increase the percentage of people with Medicare in accountable care arrangements, we are balancing incentives and participation options to serve a dual purpose of sustaining participation by existing ACOs and increasing program growth, recognizing that ACOs vary in their composition of providers/suppliers, the needs of the populations they serve, and have varying degrees of efficiency relative to their region and experience with accountable care initiatives. In this proposed rule, we are building on the existing Shared Savings Program benchmarking methodology by proposing modifications to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance on their benchmarks, to address the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks, and to support the business case for ACOs serving high risk and high dually eligible populations to participate, which will help sustain participation and grow the program. Additionally, we are proposing modifications to the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment. The changes we are proposing to the benchmarking methodology used in the Shared Savings Program would align with our consideration of more long-term benchmarking concepts that would move toward the use of administratively set benchmarks in order to grow and sustain long term program participation as discussed in the Request for Information. We are also proposing to expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings even if they do not meet the minimum savings rate (MSR) to allow for investments in care redesign and quality improvement activities among less capitalized ACOs.

We are proposing changes to the quality reporting and the quality performance requirements that are responsive to interested parties' feedback, and designed to support the transition of ACOs to all payer quality measure reporting. These proposals include reinstitution of a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, regardless of how they report quality data, and to revise the approach for determining shared losses for ENHANCED track ACOs. We are proposing to implement a health equity adjustment to an ACO's quality performance score to recognize high quality performance by ACOs with high underserved populations. We are also proposing to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option. We are soliciting input from interested parties to inform future rulemaking through requests for information addressing social determinants of health in ACO populations, and the addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) survey questions. We are also proposing to resolve a gap in our current policy for benchmarking quality measures reported through the CMS Web Interface.

We are proposing changes that are important for improved operations of the Shared Savings Program, including policies to reduce ACO administrative burden. Specifically, we are proposing to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating materials to beneficiaries and ACO participants, and modifications to streamline the SNF 3-day rule waiver application review process. We are also proposing modifications to the beneficiary notification requirements, including to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period, with a proposed follow-up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice. Further, we are proposing to revise the data sharing requirements to recognize ACOs structured as organized health care arrangements (OHCAs) for data sharing purposes.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 et seq.) by adding section 1899 of the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of

growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS final rule and the CY 2022 PFS final rule for a summary of policies finalized in prior PFS rules (84 FR 40705 and 86 FR 65253). In the CY 2022 PFS final rule (86 FR 65253 through 65306), we finalized changes to Shared Savings Program policies, including to amend the reporting requirements under the APM Performance Pathway (APP) for performance year 2022 and subsequent

performance years, to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for performance year 2023, to update the definition of primary care services used in beneficiary assignment at § 425.400(c), to revise the repayment mechanism arrangement policy, to streamline the application process, and to amend the beneficiary notification process.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.G.2. through III.G.6. of this proposed rule, we propose modifications to the Shared Savings Program's policies. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

• Allow low revenue ACOs, inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program (that is, not a renewing or re-entering ACO) to receive AIPs based on assigned beneficiary dual eligibility status and ADI national percentile rank of the census block group in which the beneficiary resides (section III.G.2.a. of this proposed rule). Advance investment payments would include a one-time fixed payment of $250,000 and quarterly payments for the first 2 years of an ACO's 5-year agreement period. Quarterly payments would be based on a risk factors-based score set to 100 if the beneficiary is dually eligible for Medicare and Medicaid or set to the ADI national percentile rank (an integer between 1 and 100) of the census block group in which the beneficiary resides if the beneficiary is not dually eligible, with higher payment amounts for assigned beneficiaries with a higher risk factors-based score.

• Allow ACOs applying to the program that are inexperienced with performance-based risk to participate in one 5-year agreement under a one-sided shared savings model, in order to provide these ACOs more time to invest in infrastructure and redesigned care processes for high quality and efficient health care service delivery before transitioning to performance-based risk (section III.G.2.b.(2) of this proposed rule).

• Revise the limitation on the number of agreement periods an ACO can participate in BASIC track Level E (section III.G.2.b.(3) of this proposed rule).

• Revise the policies for determining beneficiary assignment (section III.G.3. of this proposed rule).

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c).

++ Identify how CMS certification numbers will be used in beneficiary assignment.

• Revise the quality reporting and the quality performance requirements for performance year 2023 and subsequent performance years (section III.G.4. of this proposed rule).

++ Establish an alternative quality performance standard for ACOs that do not meet the quality performance standard to share in savings at the maximum rate by reinstating a sliding scale approach for determining shared savings for ACOs, regardless of how they report quality data and revise the approach for determining shared losses for ENHANCED track ACOs.

++ Establish a health equity adjustment that would upwardly adjust an ACO's quality performance score, to reward ACOs that report all-payer eCQMs/MIPS CQMs, that are high performing on quality, and serve a high proportion of underserved beneficiaries. This proposed adjustment would add up to 10 bonus points to the ACO's MIPS quality performance category score. The resulting health equity adjusted quality performance score would be used to determine whether the ACO meets the quality performance standard set at the 30th percentile (for performance year 2023) or 40th percentile (for performance year 2024 and subsequent years) across all MIPS quality performance category scores; the final sharing rate for calculating shared savings payments under the BASIC track and the ENHANCED track for an ACO that meets the proposed alternative quality performance standard allowing for application of a sliding scale based on quality performance; and the shared loss rate for calculating shared losses under the ENHANCED track under the proposed modified approach to scaling shared losses. It would also be used when applying the extreme and uncontrollable circumstances policy for ACOs that report quality data via the APP and meet data completeness and case minimum requirements.

++ Extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option.

++ Change the nomenclature of the administrative claims measure Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS to Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions to align with the MIPS program.

++ Clarify use of unweighted MIPS Quality performance category scores to determine the quality performance standard under the Shared Savings Program.

++ Clarify our policies on reopenings to address changes to MIPS quality performance category scores.

++ Establish policies for benchmarking quality measures reported through the CMS Web Interface for performance year 2022 through performance year 2024.

• Revise the benchmarking methodology to reduce the effect of ACO performance on ACO historical benchmarks, increase opportunities for ACOs caring for medically complex, high cost beneficiaries, and strengthen incentives for ACOs to enter and remain in the Shared Savings Program, and meet the programmatic goals of improving quality of care and lowering growth in FFS expenditures:

++ Incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in this proposed rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark and address increasing market saturation by ACOs in a regional service area (section III.G.5.c.(3) of this proposed rule).

++ Adjust benchmarks to account for prior savings, helping to mitigate lowering of an ACO's benchmark over time by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures from the previous agreement period (section III.G.5.c.(4) of this proposed rule).

++ Reduce the impact of negative regional adjustments on ACO benchmarks by reducing the cap on negative regional adjustments and gradually decreasing the negative

regional adjustment amount as an ACO's weighted-average prospective HCC risk score increases, or the proportion of dually eligible Medicare and Medicaid beneficiaries increases, or both (section III.G.5.c.(5) of this proposed rule).

- Change how we calculate regional factors used in benchmarking to increase internal consistency of benchmark calculations for ACOs under prospective beneficiary assignment by using an assignment window that is consistent with an ACO's selected assignment methodology to identify the assignable population used to calculate regional FFS expenditures (section III.G.5.d. of this proposed rule).
- Revise how we apply the existing 3 percent cap on positive prospective HCC risk score growth to better account for medically complex, high cost populations while continuing to guard against coding initiatives (section III.G.5.e. of this proposed rule).
- Increase opportunities for low revenue ACOs participating in the BASIC track to share in savings by expanding the criteria ACOs can meet to qualify for shared savings payments as described in § 425.605 (section III.G.5.f. of this proposed rule).
- Discuss ongoing considerations regarding the impact of the PHE for COVID–19 on ACO expenditures (section III.G.5.g. of this proposed rule), although there are no associated proposed revisions to the regulations at this time.
- Exclude the proposed new supplemental payment under the Medicare Hospital Inpatient Prospective Payment System (IPPS) for Indian Health Service (IHS)/Tribal hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program (section III.G.5.h. of this proposed rule).
- Remove the requirement to submit marketing materials prior to use (section III.G.6.b. of this proposed rule). ACOs would be required to submit marketing materials only upon request from CMS, but we would retain the requirement that an ACO must discontinue use of any marketing materials or activities for which CMS has issued a notice of disapproval.
- Amend the beneficiary notification requirements to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period, with a follow up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice and occurring no later than 180 days following the date that the standardized written notice was provided to the beneficiary (section III.G.6.c. of this proposed rule).
- Amend the beneficiary notification requirements to clarify that ACOs and ACO participants are required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services (section III.G.6.c. of this proposed rule).
- Remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver and replace with a requirement that an ACO submit an attestation that it has established the narratives and will make them available to CMS upon request (section III.G.6.d. of this proposed rule).
- Amend regulations to recognize ACOs structured as OHCAs for data sharing purposes (section III.G.6.e. of this proposed rule).

We also describe several comment solicitations:

- As discussed in section III.G.4. of this proposed rule and elsewhere in this proposed rule, we are seeking comment on two potential social determinants of health (SDOH) measures for future measure development, and the addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions.
- In section III.G.7. of this proposed rule, we seek comment on an alternative approach to calculating ACO historical benchmarks that would use administratively-set benchmarks that are decoupled from ongoing observed FFS spending.

In combination, the Shared Savings Program proposals are anticipated to grow participation particularly from ACOs serving beneficiaries with greater needs and higher baseline spending. The incentive for ACOs to reduce spending over multiple agreement periods is also expected to be bolstered, for example by reducing the weighting on the regional component of the benchmark update and by providing a prior savings adjustment at rebasing. A further change will prevent an assignment bias from inflating benchmark adjustments for ACOs electing prospective assignment. In summary, we project a $15.5 billion decrease in spending on benefits (that is, savings from efficiency) and $650 million in higher net shared savings payments to ACOs, or $14.8 billion lower overall spending compared to the program baseline (which would have been projected to be a $4.2 billion net cost absent these changes).

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: allowing for AIPs as described in section III.G.2. of this proposed rule: the proposed modifications to the calculation of the shared loss rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard as described in section III.G.4. of this proposed rule; use of the ACPT/national-regional three-way blended benchmark update factor as described in section III.G.5.c.(3) of this proposed rule; the expansion of the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act as described in section III.G.5.f. of this proposed rule; and the exclusion of the proposed new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program as described in section III.G.5.h. of this proposed rule. As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of

the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Shared Savings Program Participation Options

a. Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

(1) Background

In the November 2011 final rule (76 FR 67969), we estimated an average of $0.58 million for the start-up investment costs and $1.27 million in ongoing annual operating costs for an ACO participating in the Shared Savings Program. This can be a substantial investment particularly for a small organization or an organization caring for underserved or more medically complex patients. The CMS Innovation Center has tested two models designed to support new ACOs in joining and succeeding in the Shared Savings Program. The Advance Payment (AP) ACO Model operated from 2012 to 2015, and the AIM operated from 2015 to 2018. The models tested whether up-front payments would increase participation in the Shared Savings Program by ACOs serving rural or underserved regions. The models also tested whether such payments would improve quality or reduce Medicare spending without negatively affecting quality.[169] Both models operated by pre-paying shared savings to ACOs participating in the Shared Savings Program and later recouping such amounts from earned shared savings.

The AP ACO model tested whether the pre-payment of shared savings would increase participation in the Shared Savings Program by smaller providers and suppliers in rural and underserved areas, and whether these payments would allow ACOs to improve care for beneficiaries, generate Medicare savings more quickly, and increase the amount of total Medicare savings.[170] The eligibility standards for the AP ACO model required that an ACO enter the Shared Savings Program in April 2012 or July 2012. The ACO also had to meet one of the following standards: (1) not include any inpatient facilities and have less than $50 million in total annual revenue; or (2) not include any inpatient facilities other than critical access hospitals (CAHs) and/or Medicare low-volume rural hospitals and have less than $80 million in total annual revenue.[171] Prepaid shared savings included an up-front payment of $250,000 and a one-time payment of $36 per beneficiary, followed by an $8 per beneficiary per month payment for 2 years. AP ACOs received between $1.3–$2.7M in total prepaid shared savings.[172] CMS recovered pre-paid shared savings from an ACO's earned shared savings only if the ACO terminated before 3 years, in which case the ACO was required to immediately repay its prepaid shared savings payments in full.[173]

AIM tested whether the pre-payment of shared savings helped to recruit and accelerated favorable outcomes for new ACOs in the Shared Savings Program from rural, low-penetration and underserved geographies.[174] There were two cohorts of AIM, referred to as Test 1 and Test 2. The eligibility standards to join Test 1 of AIM required that an ACO be: (1) new to the Shared Savings Program; (2) not include a hospital unless it was a critical access hospital or a small Inpatient Prospective Payment System (IPPS) hospital; and (3) not owned or operated by a health plan.[175] The prepaid shared savings amounts were distributed and recouped in the same amounts and manner as the AP ACO model for the majority of model participants.[176] ACOs joining Test 2 of AIM were not new to the Shared Savings Program and were required to directly repay any unrecouped prepaid shared savings at the end of their second Shared Savings Program agreement period. Conclusions from Test 2 of AIM were unable to be drawn due to low participation.[177] All further references to AIM refer to Test 1 of the model, unless otherwise specified.

The results of the Innovation Center's evaluation of the AP ACO Model were inconclusive regarding the impact on quality or cost of care. While most ACOs included in the test continued to participate in the Shared Savings Program after the AP ACO Model ended, the Model did not significantly improve the quality or cost of care when compared to care provided outside the Shared Savings Program.[178] The results of the evaluation of AIM, however, found that the model was successful in meeting both its goals. AIM successfully encouraged ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present.[179] The AIM Model also generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and ACOs' earned shared savings.[180] AIM did not reduce the quality of care provided to beneficiaries.[181]

We have received continued interest in the AIM and AP ACO models and ongoing requests to implement policies with similar up-front and ongoing payments for ACOs newly participating in the Shared Savings Program. Interested parties believe these models were valuable for transitioning small and rural practices into ACOs and believe there is ongoing need for this type of support. We agree, and we also believe that the Shared Savings Program should provide an entry point for all willing organizations who wish to move towards providing value-driven healthcare.

Section 1899(i) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act

[169] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model (updated January 10, 2013), available at *https://innovation.cms.gov/files/fact-sheet/advanced-payment-aco-model-fact-sheet.pdf*; Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014), available at *https://innovation.cms.gov/files/x/aim-rfa.pdf.*

[170] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model (updated January 10, 2013), available at *https://innovation.cms.gov/files/fact-sheet/advanced-payment-aco-model-fact-sheet.pdf.*

[171] Centers for Medicare & Medicaid Services, Advance Payment Accountable Care Organization (ACO) Model Application Process (updated January 5, 2012), available at *https://innovation.cms.gov/files/slides/advance-payment-model-aco-odf-application-process-slides.pdf.*

[172] L&M Policy Research, Evaluation of CMMI Accountable Care Organization Initiatives: Advance Payment ACO Final Report 39–41 (November 25, 2016), available at *https://innovation.cms.gov/files/reports/advpayaco-fnevalrpt.pdf.*

[173] Ibid at 14.

[174] Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014), available at *https://innovation.cms.gov/files/x/aim-rfa.pdf.*

[175] Ibid.

[176] Ibid.

[177] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

[178] L&M Policy Research, Evaluation of CMMI Accountable Care Organization Initiatives: Advance Payment ACO Final Report 39–41 (November 25, 2016), available at *https://innovation.cms.gov/files/reports/advpayaco-fnevalrpt.pdf.*

[179] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

[180] Ibid. at 39.

[181] Ibid. at 57–60.

so long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We are interested in using the learnings from AIM and incorporating critical design features of AIM into the Shared Savings Program more broadly with the goals of increasing participation in the program by easing up-front costs for inexperienced, low revenue ACOs and supporting these ACOs in providing accountable care for underserved beneficiaries. We believe that advance payments of shared savings will improve health equity outcomes for Medicare beneficiaries by increasing Shared Savings Program participation in underserved regions and improving the success of ACOs in achieving shared savings and meeting quality metrics. Consequently, in accordance with the authority provided to the Secretary by section 1899(i) of the Act, we are proposing to make advance shared savings payments, referred to herein as advance investment payments (AIPs), to certain ACOs participating in the Shared Savings Program to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program. Such payments would be made pursuant to the standards we propose to establish in new § 425.630.

We envision that this new payment option would distribute AIPs to ACOs for 2 years in order to reduce the financial barriers encountered by small providers and suppliers as they join the Shared Savings Program. These payments would be recouped from any shared savings the ACO earned. Funding the ACOs for 2 years would align with the policy in AIM. The AIPs are designed to reduce up-front costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program.

Section 1899(i)(3)(A) of the Act requires CMS to determine that AIPs will improve the quality and efficiency of items furnished to Medicare in order to make such payments. We believe that AIPs meet this standard because such payments would be modeled on the AIM payments, which were shown to improve the quality and efficiency of care. The AIM evaluation report concluded that AIM successfully encouraged ACOs to form in geographic areas where ACOs may not otherwise have formed, the up-front funding provided by CMS assisted in the formation of the ACOs, and there was a reduction in Medicare spending and utilization without a reduction in the quality of care provided or patient and caregiver experiences.[182] The AIM evaluation found that, across all AIM Test 1 ACOs, the model reduced per beneficiary per month (PBPM) total Medicare spending by an estimated $28.21 in PY1, $36.94 in PY2, and $38.73 in PY3 compared to beneficiaries in the AIM ACOs' non-ACO FFS market comparison group.[183] The estimates translated to an aggregate Medicare spending reduction of $131.0M in 2016, $187.7M in 2017, and $207.7 in 2018.[184]

Section 1899(i)(3)(B) of the Act requires CMS to determine that AIPs, when implemented in combination with existing modifications made to the Shared Savings Program payment model specified in section 1899(d) of the Act, will not result in additional program expenditures. The addition of AIP meets this standard. Please review section VI.E.7 of this proposed rule for a fuller discussion of the financial impact of the Shared Savings Program payment model, including the findings necessary to demonstrate compliance with section 1899(i)(3)(B) of the Act.

We intend to periodically reassess whether a payment model established under section 1899(i)(3) of the Act, including the payment of advance investments, continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. If we determine that the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the payment model results in net program costs, we would undertake additional notice and comment rulemaking to make adjustments to our payment methodology to assure continued compliance with the statutory requirements.

(2) Eligibility

In October of 2021, CMS outlined a renewed vision and strategy for how the Innovation Center will drive health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries.[185] We believe accountable care reduces fragmentation in patient care and lowers costs by giving providers and suppliers the incentives and tools to deliver high-quality, coordinated, team-based care. In partnership with the Innovation Center and in support of our shared goal of increasing the number of beneficiaries in a care relationship with accountability for quality and total cost of care, we are proposing broad eligibility requirements for AIPs that will lower the barrier of entry to the Shared Savings Program for low revenue ACOs who are inexperienced with risk.

As discussed above, the AIPs are designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program. Building upon AIM's success with new ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives, we propose to limit the eligibility for these AIPs to these same groups. Our experience administering the Shared Savings Program suggests that re-entering and renewing ACOs have APM experience and would not need, or benefit as significantly from, the start-up funds that AIPs provide because they have already invested in creating an ACO. Additionally, we do not have data from our experience with AIM to conclude that previously established ACOs need or benefit from up-front shared savings. The final evaluation report for AIM could not draw conclusions for AIM Test 2 ACOs, which involved only previously established ACOs, because of the small number of AIM Test 2 ACOs and the variation in results between them. Six AIM Test 2 ACOs started AIM in April 2015 or January 2016. Two AIM Test 2 ACOs ceased participating in the Shared Savings Program at the end of 2015, leaving four AIM Test 2 ACOs evaluated in each of three performance years.[186]

We are proposing eligibility criteria modified from the AIM eligibility criteria. The eligibility standards to join Test 1 of AIM required that an ACO be: (1) new to the Shared Savings Program; (2) not include a hospital unless it was a critical access hospital or a small IPPS hospital; and (3) not owned or operated by a health plan.[187] The model also

[182] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 2–3 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

[183] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 2 (September 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

[184] Ibid. at 41.

[185] *https://innovation.cms.gov/strategic-direction.*

[186] Centers for Medicare & Medicaid Services, ACO Investment Model (AIM) Final Evaluation Report (September 2020) available at *https://innovation.cms.gov/data-and-reports/2020/aim-finalannrpt-perspective.*

[187] Centers for Medicare & Medicaid Services, Accountable Care Organization Investment Model (AIM) Request for Applications (October 14, 2014),

Continued

prioritized ACOs in rural locations and those in locations with low ACO penetration through the use of scoring criteria.[188] We believe certain eligibility modifications are necessary to scale advance payments from a model to a regular component of the Shared Savings Program and to align with the Innovation Center's stated vision for health care transformation. As AIM was only available to a limited number of ACOs, it relied on scoring criteria in addition to its eligibility standards to select the highest scoring applicants. The Shared Savings Program does not have a similar limitation; therefore, we are proposing more inclusive eligibility criteria.

We are also broadening the eligibility criteria compared to AIM to reflect our belief that it is important to provide an incentive for providers and suppliers who serve high need beneficiaries in all areas to form ACOs. Similar to AIM, the Shared Savings Program intends to encourage the formation of new ACOs in rural areas; however, unlike AIM we also want to recognize that there are underserved beneficiaries who reside in urban areas who can also benefit from the high-quality coordinated care an ACO can provide. Additionally, underserved beneficiaries may receive care from providers and suppliers within a geographic area with high alternative payment model (APM) penetration. Generally, such providers and suppliers and the beneficiaries they serve are not or have not been part of an ACO previously. Therefore, we do not believe we should limit the opportunity for an ACO to receive AIPs to ACOs in only rural communities or in areas with low ACO penetration.

We propose to establish the eligibility criteria for AIPs in § 425.630(b). Specifically, we propose that CMS must determine that an ACO meets all of the following criteria for the ACO to be eligible to begin receiving AIPs:

- The ACO is not a renewing ACO or re-entering ACO (as such terms are defined under § 425.20).
- The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track glide path and is eligible to participate in the Shared Savings Program.
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.
- The ACO is a low revenue ACO.

AIM required applicants to demonstrate an exceptional need for prepaid shared savings. In the Shared Savings Program, the definition of low revenue is a similar criterion for determining ACO funding needs. Under § 425.20, a low revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available. Low revenue ACOs tend to be small, physician-only ACOs that are less well capitalized organizations. These ACOs may be encouraged to participate and remain in the program based on the availability of additional incentives, such as the opportunity to receive AIPs.

We are proposing conforming changes to § 425.611(c)(4) to limit eligibility to low revenue ACOs. In accordance with § 425.611(c)(4), we adjust Shared Savings Program calculations to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episodes of care for treatment of COVID–19 from expenditure and revenue calculations for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO and determining an ACO's eligibility for participation options. We are proposing to revise § 425.611(c)(4) to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episodes of care for treatment of COVID–19 from expenditure and revenue calculations for purposes of determining an ACO's eligibility to receive AIPs.

We propose to limit eligibility to ACOs applying to participate under any level of the BASIC track glide path because this participation option is indicative of an ACO's inexperience with performance-based risk. ACOs in the BASIC track are typically less experienced with risk and are more likely to benefit from up-front funding or ongoing financial assistance.

In summary, we are proposing to create a new paragraph in § 425.100(d) to establish that an ACO may receive AIPs. We are also proposing in § 425.630(b) to specify the eligibility criteria for an ACO to begin receiving receive AIPs, and we are proposing conforming changes to § 425.630(c)(4). We seek comments on these proposals.

(3) Application Procedure & Contents

We propose to address the process for an ACO to apply for AIPs in § 425.630(c). Specifically, we propose that, to obtain a determination regarding whether an ACO may receive AIPs, the ACO must submit, as part of its application to participate in the Shared Savings Program, complete supplemental application information in the form and manner and by a deadline specified by CMS. The application cycle for AIPs would be conducted as part of and in conjunction with the Shared Savings Program application process under § 425.202 with instructions and timeline published through the Shared Savings Program website. We propose the initial application cycle to apply for AIPs would be for a January 1, 2024, start date. As noted in section III.G.2.a.(2) of this proposed rule, ACOs currently participating in the Shared Savings Program or applying to renew their participation agreement would not be eligible to apply. We intend to provide further information regarding the process, including the application and specific requirements such as the deadline for submitting applications, through subregulatory guidance and will also provide a feedback process to afford an opportunity for the applicant to clarify or revise its application.

We propose in § 425.630(d)(1) that an ACO must submit sufficient information for CMS to determine whether the ACO is eligible to receive such payments. CMS would provide preliminary information to the applicant ACO about its eligibility to receive AIPs during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive AIPs at the time of final application dispositions. For example, we would provide preliminary information identifying whether an ACO is low revenue and inexperienced with performance-based risk through the ACO's application to participate in the Shared Savings Program.

We further propose at § 425.630(d)(1) that an ACO would be required to submit a spend plan as part of its application for AIPs. At § 425.630(d)(2), we propose content requirements for spend plans. We propose that the plan must identify how the ACO will spend the AIPs during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under § 425.630. In addition, we propose that the spend plan must identify the categories of goods and services that will be purchased, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS. As more fully explained in section III.G.2.a.(4) of this proposed rule, we are

available at *https://innovation.cms.gov/files/x/aim-rfa.pdf.*

[188] Ibid.

proposing at § 425.630(e)(4) to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs. Accordingly, we are also proposing at § 425.630(d)(2)(iii) that the spend plan must include a statement that the ACO has established a separate designated account for the deposit and expenditure of all AIPs in accordance with § 425.630(e)(4).

We do not intend for the proposed spend plan to create a benchmark requirement against which we would hold the ACO accountable. Instead, we intend it to aid CMS in tracking ACO progress toward implementing their spend plan and any challenges or changes in strategy that occur following their receipt of AIPs. We believe that ACOs have the flexibility to better understand their needs over time and evolve their spending accordingly.

While we do not intend an ACO's spend plan to limit it to specific uses of AIPs within the broad categories of acceptable uses, we would reserve the right to terminate an ACO's ability to receive the advance incentive payments if it is not in compliance with requirements of the Shared Savings Program (see our proposal described in section III.G.2.a.(7).(b) of this proposed rule). In addition, by certifying its application under § 425.202(a)(2), the ACO certifies that the information contained in the application, including the information necessary to determine eligibility for AIPs, is accurate, complete, and truthful.

We propose at § 425.630(d)(3) that we would review the information submitted in the ACO's application to determine whether an ACO meets the eligibility criteria and other requirements for AIP and would approve or deny the application for AIPs accordingly. We would review the ACO's Shared Savings Program application simultaneously with the supplemental information in its AIP application. We note that the denial of an AIP application would be subject to reconsideration review in accordance with the standards specified in subpart I of part 425.

In addition, we are proposing at § 425.630(d)(3) that CMS may review the spend plan at any time and require the ACO to make changes to its spend plan comply with § 425.630(e)(1) as a result of that review. Examples of permitted uses are described in section III.G.2.a.(4) of this proposed rule. Under our proposal, if the ACO fails to provide a spend plan that complies with § 425.630(e), CMS could terminate the ACO's AIPs pursuant to § 425.630(h)(1)(i) and take other remedial action under § 425.216 or § 425.218.

As discussed in section III.G.2.a.(7).(a) of this proposed rule, we are also proposing to update our public reporting requirements under § 425.308 by adding new paragraph (b)(8) to require an ACO to publicly report its spend plan. We propose to require that the ACO post on its dedicated public reporting web page: (1) the total amount of AIPs received from CMS for each performance year; (2) the ACO's spend plan; and (3) an itemization of how the AIPs were actually spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan as submitted under § 425.630(d)(1), and such other information as may be specified by CMS. The public reporting template that CMS provides to ACOs annually would be updated to reflect the new information categories that an ACO must report.

We propose to add § 425.630(c) and (d) to establish standards for the contents of an application to be determined eligible for AIPs as well as the procedures for filing such an application. We solicit comments on these proposals.

(4) Use and Management of Payments

Under section § 425.308(b)(4), ACOs are required to publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the goals of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion of shared savings distributed among ACO participants. Although ACOs are required to report this information, our regulations do not require an ACO to spend its shared savings in any particular way. However, given the purpose of AIPs, the fact that they are made before any shared savings are actually earned by an ACO, and our proposed limitations on the recovery of these funds in the absence of any earned shared savings, we propose at § 425.630(e) to specify how an ACO may use AIPs.

Similar to our experience with AIM, AIPs are intended to provide the means to build the ACO's population health management capabilities, including the provision of accountable care for underserved beneficiaries. AIPs are not intended to sit idle in an investment account or to serve purposes unrelated to the goals of AIPs. We propose at § 425.630(e) that AIPs must be used to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. We emphasize, however, that AIP amounts are advance shared savings, and not payment or reimbursement for items or services under the three specified categories. We propose that expenditures of AIPs must comply with the beneficiary incentive provision at § 425.304 and all other applicable laws and regulations. Our proposal is intended to provide ACOs with flexibility to use payments within three specified categories of allowable uses. We solicit comment on whether there are additional categories of expenses that should be permitted in light of the purposes of AIPs. We will monitor how ACOs are spending these funds and will revisit these categories in future rulemaking if additional flexibilities or boundaries are required.

We recognize that there are many ways to improve population health management and support the provision of accountable care for underserved beneficiaries. The most effective ways will vary by ACO. We believe ACOs know best the needs of their populations and how to use funds to meet program goals. We offer the following examples of permitted uses within the three categories:

- *Increased staffing.* Hiring nurse case managers or other relevant support staff to implement screening for social determinants of health (SDOH); hiring community health workers, certified peer recovery specialists, other health care professionals with training in delivering culturally and linguistically tailored services; hiring a health equity officer; hiring behavioral health clinicians and case managers to integrate behavioral health treatment into the primary care setting; hiring oral health providers to integrate dental services into the primary care setting; or encouraging partnerships with healthcare systems and local, community-based organizations to increase organizational capacity to identify and address SDOH and connect individuals with culturally and linguistically tailored, accessible health care services, supports, and information at an appropriate literacy level.
- *SDOH strategies.* Examples include developing or securing transportation services; housing-related services to address housing insecurity or homelessness, home or environmental modifications to support a healthy lifestyle, legal aid services to help patients' address social needs, employment-related services, food-

related services, utilities-related supports, services to support personal safety, services to reduce social isolation, services to help patients cope with or address financial strain or poverty, patient caregiver supports, providing remote access technologies, telemonitoring, and meals; ensuring individuals are able to access culturally and linguistically tailored, accessible health care services and supports that meet their needs, partnering with community-based organizations such as Area Agencies on Aging or Centers for Independent Living to address SDOH needs; or implementing systems to provide and track patient referrals to available community-based social services that assess and address social needs, as well as enable coordination and measurement of health and social care across the community where beneficiaries reside. CMS reserves the right to review any SDOH strategies and require that the ACO make changes as a result of that review.

- *Health Care Provider Infrastructure.* Examples include investment in certified electronic health record technology (CEHRT) (including system enhancements and upgrades), connections to clinical data registries and networks that support health information exchange across disparate providers and systems involved in patient care, integration of ACO participant systems including tools to share and analyze operational and quality data, remote access technologies, telemonitoring, screening tools, case management or practice management systems to improve care coordination operations across the health and social care continuum, physical accessibility improvements, and tools to further integrate behavioral health or dental services into primary care settings.

Where we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. Such organizations are trusted entities that know the populations they serve and their communities, want to be engaged, and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a trusted source to share information.[189] They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), or the Centers for Disease Control, or other State-funded grants to provide social services. If an ACO wishes to address a social need, it is important for health providers who may not have expertise in providing social services to work with those community-based organizations that do have such expertise.

We note that the Shared Savings Program does not prohibit ACOs from partnering with community-based organizations. Currently, if a community-based organization is enrolled in Medicare, they may already be an ACO participant or ACO provider or supplier. We believe community-based organizations play an important role in identifying and addressing gaps in health equity. We hope to encourage more ACOs to partner with community-based organizations whether they provide items and services reimbursed by Medicare or not.

Regarding investments in networks that support health information exchange, we encourage ACOs to review the request for information in section II.A.3.B of this proposed rule regarding the recently released Trusted Exchange Framework and Common Agreement or TEFCA,[190] which includes discussion about how connecting to entities exchanging information under TEFCA can help to support health information exchange for a variety of use cases that may be relevant to ACOs.

We propose in § 425.630(e)(2) to prohibit the use of AIPs for any expenses that would not constitute a permitted use of the funds. Similar to the AIM model, we intend for advance investment payments to encourage the formation of new ACOs that provide care to underserved beneficiaries, not simply to fund another business venture of an established company or to furnish items or services unrelated to the ACO or the beneficiaries it serves.

Examples of prohibited uses of AIPs would include management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicare, or items or activities unrelated to ACO operations that improve the quality and efficiency of items and services furnished to beneficiaries. However, performance bonuses could be tied to successful implementation of SDOH screenings or care management guidelines, or ACOs could pay a higher salary as necessary to retain a clinician who treats underserved beneficiaries. We solicit comment on these examples of prohibited uses and whether there are additional categories of expenses that should be prohibited in light of the purposes of AIPs. We will monitor how ACOs are spending these funds and will revisit these categories in future rulemaking if additional flexibilities or boundaries are required.

Additionally, we propose that an ACO participating in Level E of the BASIC track may not use any advance shared savings payments to pay back any shared losses that it would have incurred as specified in a written notice from CMS under § 425.605(e)(2). To ensure compliance, we propose updating the annual certification requirements under § 425.302(a)(3) to require that the ACO certify that the payments were disbursed only for allowable uses. Level E of the BASIC track is currently an Advanced APM, and we expect it to remain an Advanced APM in future years. The level of risk in an Advanced APM is, by definition at § 414.1415(c), greater than a nominal amount; therefore, we are proposing that an ACO eligible to receive advance shared savings payments that is willing to take on such additional risk must remain liable for any losses incurred regardless of advance payments received.

We propose at § 425.630(e)(4) to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs and from which all disbursements of such funds are made only for allowable uses. This would allow us to monitor whether the funds are used only for allowable uses and to ensure that AIPs do not pay for any prohibited uses under § 425.630(e)(2). We note that CMS would deposit AIPs into the same account used for the deposit of shared savings payments; that account must be specified in an ACO's Electronic Funds Transfer form submitted with its application. We propose that, upon receipt of AIPs, the ACO must immediately deposit the funds into the separate account designated for maintaining AIPs.

As noted in section III.G.2.a.(4) of this proposed rule, we propose that the ACO's spend plan must also include a statement that the ACO has established a separate account for purposes of

[189] *https://www.phe.gov/emergency/events/COVID19/atrisk/returning-to-work/Pages/default.aspx.*

[190] For more information, see *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement-tefca.*

segregating AIPs. Additionally, we propose to update our annual certification requirements under § 425.302 by adding new paragraph (a)(3)(iv) to require an ACO to certify at the end of each performance year that it has moved all AIPs received during that performance year into a designated AIP account, where the funds remained until spent as required under § 425.630(d).

(5) Advance Investment Payment Methodology

In AIM, prepaid shared savings included an up-front payment of $250,000 and a one-time payment of $36 per beneficiary, followed by a monthly payment of $8 per beneficiary per month for the first 2 performance years of an AIM ACO's agreement period. According to the AIM evaluation, AIM ACO leadership conveyed through interviews and the ACO Web survey that they wanted to join the Shared Savings Program to gain experience in delivering value-based care and remain independent, and that AIM funds were critical to building the infrastructure needed to implement their ACOs.[191] The evaluation also found that these new AIM ACOs consistently demonstrated greater reductions in key Medicare spending categories and related utilization compared to similar non-AIM Shared Savings Program ACOs.[192] Furthermore, there were greater reductions in all components of Medicare spending examined, including acute inpatient hospitalizations, outpatient visits, skilled nursing facility care, and home health use. The evaluation did not find reductions in Medicare spending and utilization to be offset by reductions in the quality of care provided or patient and caregiver experiences.

We are proposing to provide an ACO that CMS determines meets the eligibility criteria described in section III.G.2.a.(2) of this proposed rule with AIPs during the first 2 performance years of the ACO's participation agreement. We are proposing that AIPs are comprised of two types of payments: a one-time payment of $250,000 and eight quarterly payments based on the number of assigned beneficiaries, capped at 10,000 beneficiaries.

The proposed $250,000 one-time payment is informed by the AIM payment structure, which offered a $250,000 up-front fixed payment to new AIM ACO participants starting in the Shared Savings Program in 2015 and 2016. Under the model, the upfront fixed payment reflected the estimated upfront investment requirements to establish ACOs. Here, we are proposing a $250,000 one-time AIP because we believe that such a payment would similarly support an ACO in addressing the upfront investment requirements for a new, low revenue and inexperienced ACO to join the Shared Savings Program. We have experience with a fixed $250,000 upfront payment from AIM, which served ACOs that are similar in many ways to ACOs that would be served by the proposed AIPs. Furthermore, we believe that initial ACO start-up costs do not vary significantly by the size of an ACO or by the underlying level of risk of an assigned beneficiary population. However, we are considering alternative values of the one-time payment, such as allowing the one-time payment to vary by ACO based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both. We seek comment on the proposal to provide ACOs with a one-time payment of $250,000, as well as these alternatives.

The quarterly payments are informed by our experience in AIM where ACO participants had variable costs for clinical care management activities, such as clinical staff, which were supported by the per beneficiary per month payments offered to them in the model.

We are proposing to make payments on a quarterly basis to balance providing ACOs with predictable cash flow to participate in the Shared Savings Program and simplifying operations for CMS. We considered other options for the frequency of the payments, such as monthly payments as were tested in AIM, or annual payments. Making more frequent payments, such as on a monthly basis, would result in additional operational burden for CMS because we would need to calculate the payments more frequently. Because the Shared Savings Program operates on a larger scale than AIM did, the burden of administering monthly advance payments is not feasible. Moreover, we believe that monthly payments offer little additional benefit to ACOs relative to quarterly payments. We are not proposing a single annual payment as we believe the benefit to ACOs of consistent payments on a quarterly basis outweighs the administrative costs of calculating quarterly payments. We seek comment on the proposed schedule of the AIPs to ACOs.

We propose to determine the value of an ACO's upcoming quarterly payment amount prior to the start of the quarter based on the latest available assignment list for the performance year (see Table 40). We believe it is important to use the latest available assignment list because under current regulation the individual beneficiaries assigned to the ACO may change between annual and quarterly assignment runs. For ACOs under preliminary prospective assignment with retrospective reconciliation as described at § 425.400(a)(2) the assignment list is updated quarterly based on the most recent 12 months of data. For ACOs under prospective assignment as described at § 425.400(a)(3), the assignment list is updated quarterly to exclude beneficiaries that meet any of the exclusion criteria during the performance year. Therefore, we believe that using the latest available assignment list to determine the upcoming quarterly payment will best reflect the attributes of the ACO's assigned population.

TABLE 40: Proposed Advance Investment Payment Schedule

	January; Performance Year (PY) 1	April; PY 1	July; PY 1	October; PY 1	January; PY 2	April; PY 2	July; PY 2	October; PY 2
Payment type	One-Time Payment; Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment	Quarterly Payment

[191] Abt Associates, Evaluation of the Accountable Care Organization Investment Model Final Report 20 (Sep. 2020), available at *https://innovation.cms.gov/data-and-reports/2020/aim-final/annrpt.*

[192] Ibid.

We are also considering an alternative proposal for the timing of the quarterly payments calculation. Under this alternative, we would determine the ACO's quarterly payment at the start of the performance year based on the beneficiaries assigned to the ACO at the beginning of a performance year. The quarterly payment amount determined at the beginning of a performance year could remain fixed for the duration of that performance year. The total payments ACOs would receive over the course of a performance year would be known by the ACO at the start of that performance year. However, this alternative also carries the risk that CMS would underpay or overpay an ACO relative to an approach of redetermining the quarterly payment amount prior to the start of each quarter. We seek comment on this alternative proposal.

We are proposing that the quarterly payments made to ACOs would be equal to the sum of per beneficiary payments for up to 10,000 beneficiaries. The per beneficiary payment amount would vary for each beneficiary based on a risk factors-based score that we would calculate for the beneficiary. The risk factors-based score would be informed by the beneficiary's dual eligibility status and the ADI national percentile ranking of the census block group of the beneficiary's primary address, described in further detail later in this section. The quarterly payments reflect expected variable ongoing operating costs that are related to the number and risk factors of the ACO's assigned beneficiaries.

We propose to add a new § 425.630(f) to establish the frequency and payment methodology for AIPs. Specifically, we propose a one-time payment for ACOs at or near the beginning of PY 1 of the ACO's agreement period. Quarterly payments would be made each quarter for the first 2 performance years of the ACO's agreement period. We would complete the following steps to calculate the ACO's quarterly payment amount:

- *Step 1:* Determine the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the quarterly payment amount would be the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for ACOs under prospective assignment), based on the certified ACO participant list for the relevant performance year.
- *Step 2:* Assign each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified in Step 1, CMS would do the following:

++ If the beneficiary is dually eligible for Medicare and Medicaid, assign a risk factors-based score of 100.[193]

++ If the beneficiary is not dually eligible, assign a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address.

++ If the beneficiary is not dually eligible but cannot be matched with an ADI national percentile rank due to insufficient data, impute a risk factors-based score of 50.[194]

- *Step 3:* Determine a beneficiary's payment amount. For each beneficiary in the assigned population, CMS would determine the payment amount that corresponds to the beneficiary's risk factors-based score according to the per beneficiary payment amounts specified by CMS elsewhere in this section (refer to Table 42).
- *Step 4:* Calculate the ACO's total quarterly payment amount. The ACO's quarterly payment amount would be the sum of the payment amounts corresponding to each assigned beneficiary's risk factors-based score, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries, CMS would calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores.

As described earlier, a goal of AIPs is to reduce financial barriers for new, low revenue and inexperienced ACOs to join the Shared Savings Program. In addition to bringing ACOs into the program, as part of the Agency's goals to advance health equity, we are interested in using the AIPs to support ACOs in improving the care received by underserved beneficiaries. We believe that we will further the Agency's goal to advance health equity by basing the ACO's quarterly payment amount on the sum of per beneficiary payments that vary by a beneficiary's risk factors-based score, as informed by the ADI national percentile rank of the beneficiary's census block group and the beneficiary's dual eligibility status. We believe the ADI national percentile rank of the beneficiary's census block group and dual eligibility are good indicators of beneficiaries with high needs. The ADI measure is intended to capture local socioeconomic factors correlated with medical disparities and underservice, while the beneficiary level measure of dual eligibility is intended to capture socioeconomic challenges that could affect a beneficiary's ability to access care.

The ADI was developed by researchers at the National Institutes of Health with the goal of quantifying and comparing social disadvantage across geographic neighborhoods. It is a composite measure derived through a combination of 17 input variables from census data. The 17 input variables across four domains are shown in Table 41.

[193] A beneficiary is considered dually eligible if they were dually eligible for Medicare and Medicaid in any of the 12 months that correspond with the window used for assigning beneficiaries under the preliminary prospective assignment methodology. The 12-month window is described in further detail elsewhere in this section.

[194] The imputed score of 50 is described in further detail elsewhere in his section.

TABLE 41: 17 Input Variables from Census Data

Domain	Variable
Education	% Population aged 25 years or older with less than 9 years of education
	% Population aged 25 years or older with at least a high school diploma
	% Employed population aged 16 years or older in white-collar occupations
Income/Employment	Median family income in US dollars
	Income disparity
	% Families below Federal poverty level
	% Population below 150% of Federal poverty level
	% Civilian labor force population aged 16 years and older who are unemployed
Housing	Median home value in US dollars
	Median gross rent in US dollars
	Median monthly mortgage in US dollars
	% Owner-occupied housing units
	% Occupied housing units without complete plumbing
Household Characteristics	% Single-parent households with children younger than 18
	% Households without a motor vehicle
	% Households without a telephone
	% Households with more than 1 person per room

The ADI is calculated at the census block group level through the US Census Bureau's American Community Survey. Census blocks, the smallest geographic area for which the Bureau of the Census collects and tabulates decennial census data, are formed by streets, roads, railroads, streams and other bodies of water, other visible physical and cultural features, and the legal boundaries shown on Census Bureau maps. A census block group is the next level above census blocks in the geographic hierarchy and is a combination of census blocks that is a subdivision of a census tract or block numbering area. The census block group typically contains 600 to 3,000 people and is the smallest geographic entity for which the decennial census tabulates and publishes sample data. Files containing the ADI of U.S. census block groups is publicly available through the Neighborhood Atlas from the University of Wisconsin.[195] It is a relative measure that is reported at the individual block group level, typically reported by nationwide percentile (1–100) or Statewide decile (1–10), with a higher percentile indicating greater disadvantage. The relative measure reported at the census block group level is referred to as the ADI national percentile rank.

We are proposing to use the ADI national percentile rank for the census block group in which a beneficiary resides for that beneficiary's risk factors-based score if the beneficiary is not dually eligible for Medicare and Medicaid. Specifically, we are proposing to establish the ADI national percentile rank of the beneficiary's census block group derived from the beneficiary's latest mailing address in CMS data systems at the time of the calculation. Furthermore, we are proposing to use the most recently available version of the ADI. At the time of this proposed rule, the latest version available was the 2019 ADI which was based on the 2015–2019 ACS Five Year Estimates. The ADI data files are publicly available for download at *https://www.neighborhoodatlas.medicine.wisc.edu/*.

We are proposing to use the beneficiary's dual eligibility status to inform the risk factors-based score. Specifically, we are proposing that if a beneficiary is dually eligible, the beneficiary's risk factors-based score would be 100. A score of 100 would ensure that the ACO receives the maximum payment amount for each beneficiary dually enrolled in Medicare and Medicaid, which would further the Agency's goal to ensure beneficiaries with dual eligibility have full access to seamless, high quality health care.

To determine a beneficiary's dual eligibility status, we would consider the beneficiary's enrollment status in each month of a 12-month window. The 12-month window would correspond with the assignment window used for preliminary prospective assignment with retrospective reconciliation for that particular assignment run. For example, we are proposing to use PY1 Quarter 1 assignment to inform the quarterly payment we would make to the ACO in July of PY1; the preliminary prospective assignment window for that assignment run would be April 1 of the prior calendar year through March 30 of the current calendar year. Therefore, we would consider the beneficiary's dual eligibility status in each of those 12 months. If a beneficiary had zero months of dual enrollment, we would consider the beneficiary not dually enrolled. If the beneficiary had at least one month of dual enrollment in Medicare and Medicaid, we would consider the beneficiary dually enrolled.

We are considering alternatives to assigning 100 points to the beneficiary for dual eligibility status. One alternative we are considering is to calculate a beneficiary's risk factors-based score as the sum of the ADI national percentile rank of the beneficiary's census block group and 25 points if the beneficiary is dually eligible for Medicare and Medicaid. The maximum risk factors-based score would therefore be 125, and we would revise the payment amount ranges to account for a higher maximum score. We are considering 25 points for dual status because through preliminary analysis we observed that the median ADI score for the population that was aligned to Direct Contracting Entities in PY 2021 was 42 with a standard deviation of 25. Furthermore, given the

[195] The ADI data files are publicly available for download at *https://www.neighborhoodatlas.medicine.wisc.edu/*.

fact that the ADI score is a variable value and the bonus points for dual eligibility status would be fixed at 25 points, the relative weight of the 25 points is lower for beneficiaries living in a relatively highly deprived area and higher for beneficiaries in a relatively advantaged area. For example, consider one dual eligible beneficiary and one non-dual eligible beneficiary, both living in a census block group with an ADI national percentile rank of 50 (the U.S. median). The dual eligible beneficiary would receive a risk factors-based score of 75 (50 plus 25), which is 50 percent higher than the risk factors-based score of the non-dual eligible beneficiary. For a dual eligible beneficiary who lives in a census block group with an ADI national percentile rank of 70 (more deprived than the median), 25 points would increase their score by 36 percent. There are many people who do not qualify for Medicaid but still face systemic and structural barriers to care. Therefore, we believe it would be reasonable to add a relatively moderate bonus to the beneficiary's ADI national percentile rank to calculate a combined risk factors-based score that values both dual status and other structural barriers to care that also may require upfront investments by an ACO to help their assigned beneficiaries overcome. We are seeking comment on an alternative proposal to calculate the beneficiary's risk factors-based score by taking the sum of the ADI national percentile rank where the beneficiary lives and 25 points if the beneficiary is dually eligible for Medicare and Medicaid.

We are proposing per beneficiary payment amounts that increase as a beneficiary's risk factors-based score increases. The proposed per beneficiary payment amounts by range are shown in Table 42. A dually eligible beneficiary would receive a risk factors-based score of 100, which corresponds to a quarterly payment amount of $45. A beneficiary not dually eligible and residing in a census block group with an ADI in the 75th percentile would receive a risk factors-based score of 75 which corresponds to a quarterly payment amount of $40.

TABLE 42: Proposed Quarterly Per Beneficiary Payment Amounts

Risk Factors-Based Score	1-24	25-34	35-44	45-54	55-64	65-74	75-84	85-100
Per beneficiary payment amount	$0	$20	$24	$28	$32	$36	$40	$45

We calibrated the proposed per beneficiary payment amounts against the distribution of risk factors-based scores for beneficiaries assigned to ACOs in PY 2020, such that the average ACO participating in PY2020 would have received approximately the same payment value across 2 performance years as the average ACO that participated in AIM. The payments would begin at $20 and would be scaled upward by increments of 4–5 dollars as the risk factors-based score increases. We are proposing that a beneficiary with a risk factors-based score of less than 25 would have a corresponding payment of $0, as a goal of the AIPs option is to encourage formation of new ACOs that serve underserved beneficiaries. A beneficiary risk factors-based score of less than 25 would indicate that the beneficiary is not dually eligible for Medicare and Medicaid and is residing in a census block group with low area deprivation. We are proposing that any beneficiary with a risk factors-based score of 85 or higher would receive the maximum payment of $45. These beneficiaries either have dual eligibility or reside in a census block group with high area deprivation; we consider beneficiaries with these factors to represent the highest need for upfront investments in care coordination interventions by ACOs. As we gain more experience with AIPs, we would reevaluate the effectiveness of the payment amounts in Table 42 and may propose modifications in future rulemaking.

We are proposing to calculate the quarterly payment as the sum of the per beneficiary payment amounts corresponding to each assigned beneficiary, capped at 10,000 beneficiaries. The proposed 10,000 beneficiary cap is similar to what was tested in AIM. We believe a cap is necessary to insulate the Trust Funds from making extremely large quarterly payments to large ACOs. Also similar to AIM, we propose that if an ACO has more than 10,000 assigned beneficiaries, we would calculate the quarterly payment based on the 10,000 assigned beneficiaries with the highest risk factors-based scores, which would maximize the quarterly payment for the ACO.

We are proposing under the new § 425.630(f) that CMS notifies in writing each ACO of its determination of the amount of AIP. If CMS does not make any AIP, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the standards specified in subpart I of our regulations. Thus, with each quarterly payment we are proposing to provide the ACO with a report that shows our calculation of the ACO's quarterly payment amount, including the risk factors-based score we assigned to each beneficiary used as part of the calculation, and the per beneficiary payment that corresponds to that score.

We are considering alternative methodologies to calculating an ACO's quarterly payment. We are considering an approach of determining an ACO's average risk factors-based score based on all of the ACO's assigned beneficiaries. That is, we would take the sum of the risk factors-based scores for each of the ACO's assigned beneficiaries and divide by the total number of the ACO's assigned beneficiaries. In this alternative, ACOs with an average risk factors-based score above the median would have their per beneficiary payment amount scaled upward and those with an average risk factors-based score below the median would have their per beneficiary payment amount scaled downward. An ACO with an average risk factors-based score of the median would have their per beneficiary payment amount set to $30. An ACO with an average risk factors-based score greater than the median would have their per beneficiary payment amount increased by the percentage difference of the score compared to the median. For example, if the median is 50, an ACO with an average risk factors-based score of 70 would have their per beneficiary payment amount increased by 20 percent to $36 and an ACO with an average risk factors-based score of 32 would have their per beneficiary payment amount reduced by 18 percent

to $24.60. The quarterly payment would equal the per beneficiary per quarter payment amount multiplied by the number of assigned beneficiaries, capped at 10,000 beneficiaries. This alternative approach would allow us to consider the risk factors-based scores of all of an ACO's assigned beneficiaries, not only the 10,000 assigned beneficiaries with the highest risk factors-based scores, in determining the ACO's quarterly payment. We seek comment on this alternative methodology.

We also are considering an alternative proposal to identify underserved beneficiaries based on whether their mailing address is located in a Health Professional Shortage Area (HPSA) for primary care instead of the beneficiary's mailing address' ADI percentile rank. As part of the Health Resources and Services Administration's (HRSA) cooperative agreement with the State Primary Care Offices, the State Primary Care Offices conduct needs assessment in their States, determine what areas are eligible for designations, and submit designation applications to HRSA. HRSA reviews the HPSA applications submitted by the State Primary Care Offices, and—if they meet the designation eligibility criteria for the type of HPSA the application is for—designates a HPSA. HPSAs are defined under section 332(a) of the Public Health Service Act. HPSA designations identify geographic areas, population groups, or facilities within the United States that are experiencing a shortage of health care professionals. Geographic HPSAs are defined as having a shortage of providers services for the entire population within an established geographic area; population HPSAs, in which there is a shortage of providers services for a specific population subset within an established geographic area; and facility HPSAs, in which there is a shortage of providers for that include certain categories of facilities. The Health Resources and Services Administration (HRSA) is responsible for making these HPSA designations in accordance with section 332(a) of the Public Health Service Act. Under this alternative, the risk factor-based score would be based on the sum of points assigned based on whether an assigned beneficiary is residing in an area designated as a geographic HPSA, as determined by the beneficiary's mailing address, and whether a beneficiary is dually eligible for Medicare and Medicaid. As a result, there would be three different per beneficiary payment amounts based on whether an assigned beneficiary is: (1) both residing in a geographic HPSA and dually eligible for Medicare and Medicaid; (2) residing in a geographic HPSA only; or (3) dually eligible for Medicare and Medicaid only. Under this alternative, we would not provide a per beneficiary payment amount if the assigned beneficiary is not in a geographic HPSA and not dually eligible for Medicare and Medicaid. As we believe the ADI metric can support identification of beneficiaries who face a variety of social determinants to health, not only health provider shortages, we are proposing to use ADI. However, we are seeking comment on an alternative methodology of using HPSA scores.

We are also considering an alternative methodology that additionally considers whether a beneficiary receives a Part D low income subsidy from Medicare in CMS' calculation of the quarterly payment amount.[196] In this alternative, the risk factors-based score would be equal to the assigned beneficiary's ADI national percentile or 100 points if the beneficiary is dually enrolled in Medicare and Medicaid or receives a Part D low income subsidy from Medicare. We are seeking comment on this alternative methodology.

There are circumstances where a beneficiary may not have an ADI national percentile rank. In the cases where Medicare beneficiaries have a missing or partial address in our database, we will not be able to match them with a census block group. In a preliminary review of Medicare beneficiary information, less than 2 percent of beneficiaries could not be matched to a census block group due to missing or insufficient mailing address data. Additionally, under the ADI methodology approximately 2 percent of U.S. census block groups do not receive an ADI national percentile rank due to data suppression criteria. These suppression criteria include: fewer than 100 people, fewer than 30 housing units, or more than 33 percent of the population living in group quarters or missing core component variables. In our preliminary review of Medicare beneficiary information, approximately 1 percent of Medicare beneficiaries had sufficient address data, but were in a U.S. census block group without a national percentile rank due to data suppression criteria. For beneficiaries with no ADI national percentile rank due to missing or insufficient mailing address data or data suppression criteria, and are not automatically receiving a score of 100 for being a beneficiary who is dually eligible for Medicare and Medicaid, we propose to impute a value of 50 in place of the ADI national percentile rank for the purposes of determining an assigned beneficiary's risk factors-based score and per beneficiary payment amount. An imputed ADI ranking of 50 corresponds to the average national ADI ranking and would thus be the most neutral imputed value. This would avoid biasing an ACO's payments in either direction due to missing information. We seek comment on this proposal to impute a value in place of the ADI national percentile rank to address missing beneficiary information when calculating the risk factors-based score.

To summarize, we are proposing to provide an ACO with a one-time payment of $250,000 prior to the start of the ACO's first performance year. We are additionally proposing to calculate an ACO's upcoming quarterly payment prior to the start of the quarter, using the latest available assignment list. We would calculate an ACO's quarterly payment amount based on risk factors-based scores of up to 10,000 beneficiaries assigned to the ACO prior to the start of the performance year, and ACOs with more than 10,000 beneficiaries would have a quarterly payment calculated based on the 10,000 beneficiaries assigned to the ACO with the highest risk factors-based scores. We are proposing to assign a risk factors-based score for each beneficiary using the ADI national percentile rank of the beneficiary's census block group or assigning 100 points if the beneficiary is dually eligible for Medicare and Medicaid. We are proposing to impute a value of 50 in place of an ADI national percentile rank if the beneficiary is not dually eligible for Medicare and Medicaid and cannot be matched with an ADI national percentile rank due to insufficient data. Finally, we are proposing dollar value amounts that vary by risk factors-based score, in that the amounts gradually increase as the risk factors-based score increases. We seek comment on each of these proposals.

(6) Duration of Advance Investment Payment

In AIM, ACOs in the model participated in 3-year agreements in the Shared Savings Program, and they received prepaid shared savings for the first 2 years of their participation and were allowed to spend that funding over their entire 3-year agreement period. In AIM, we observed that many ACO

[196] The low-income subsidy helps people with Medicare pay for prescription drugs, and lowers the cost of Medicare prescription drug coverage. For more information about the LIS, refer to *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources.*

model participants needed the entire agreement period to be able to spend the prepaid shared savings they received under the model. Based on our experience with AIM, we are proposing that the ACOs would receive AIPs (meaning one-time payment plus quarterly payments) in the first 2 years of their participation agreement and would be permitted to spend the AIPs over their entire 5-year agreement period. The requirement that funds be spent during the agreement period furthers our goals of supporting the establishment of ACOs and delivering care to beneficiaries in a prompt manner. We are seeking public comments on our proposal to provide AIPs to ACOs for the first 2 years of the ACO's performance period, to allow ACOs to spend those payments over the duration of their 5-year agreement period, and to send a demand letter for any unspent funds at the end of the ACO's agreement period. We are proposing at § 425.630(e)(3) that an ACO may spend an AIP over its entire agreement period and must repay CMS any unspent funds at the end of its agreement period. CMS will issue a demand letter for any such amounts.

(7) Compliance and Monitoring

(a) Public Reporting and Monitoring of Spend Plan

We propose to monitor the spending of AIPs to provide CMS with a clear indication of how ACOs intend to spend AIPs, provide adequate protection to the Medicare Trust Funds, and to prevent funds from being misdirected or appropriated for activities that do not constitute a permitted use of the funds. We would do so by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against the actual spending as reported on the ACO's public reporting webpage, including any expenditures not identified in the spend plan. The reported annual spending must include any expenditures of AIPs on items not identified in the spend plan. ACOs would be required to annually report their actual expenditures via an updated spend plan on their public reporting webpage.

We believe that transparency of information in the health care sector facilitates more informed patient choice and offers incentives and feedback that help improve the quality and lower the cost of care and improve oversight with respect to program integrity. As CMS has discussed in previous final rules, improved transparency supports a number of program requirements. In particular, increased transparency is consistent with and supports the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it.

Therefore, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's use of AIPs to be available to the public. Making this information available will provide both Medicare beneficiaries and the general public with insight into the use of AIP funds by an ACO. Accordingly, we are proposing to modify § 425.308 to require that an ACO annually report on its public reporting webpage information regarding AIPs. Specifically, under proposed new § 425.308(b)(8), we are proposing that, for each performance year, an ACO would be required to report (in a standardized format specified by CMS) its spend plan, the total amount of AIPs received, and an itemization of how any AIPs were actually spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan as submitted under § 425.630(d)(1), and such other information as may be specified by CMS. We propose that this itemization would include expenditures not identified or anticipated in the ACO's submitted spend plan, and any amounts remaining unspent. Under this proposal, if CMS determined that an ACO had disbursed AIPs for a prohibited use under proposed § 425.630(e)(2), CMS could terminate the ACO's receipt of AIPs under proposed § 425.630(h), as discussed later in this section. Any AIPs that are unspent at the end of the ACO's agreement period must be repaid to CMS under proposed § 425.630(e)(3), as discussed above. Additionally, CMS could take compliance action as specified in §§ 425.216 and 425.218 if an ACO spent the funds on a prohibited use or if have unspent funds at the end of the agreement period. We seek comment on all aspects of this proposal.

We note that under existing § 425.314, ACOs would be required to retain adequate books and records to ensure that CMS has the information necessary to conduct appropriate monitoring and oversight of ACOs' use of AIPs (for example, invoices, receipts, and other supporting documentation of AIP disbursements). To protect the program and the Medicare Trust Funds, we may use our authority under §§ 425.314 and 425.316 to audit ACO compliance with Shared Savings Program requirements and to monitor the performance of ACOs, respectively. We will conduct audits as necessary to monitor and assess an ACO's use of AIPs and compliance with other requirements related to such payments.

(b) Monitoring for Changes in ACO Experience With Risk and ACO Revenue

As described in section III.G.2.a.(2) of this proposed rule, under the new § 425.630(b) ACOs must meet the following basic criteria to be eligible for AIPs:

- The ACO is not a renewing or re-entering ACO, as defined under § 425.20.
- The ACO is applying to participate under any level of the BASIC track glide path as specified under § 425.600(a)(4)(i)(A).
- The ACO must be inexperienced with performance-based risk Medicare ACO initiatives, as defined by § 425.20.
- The ACO must be a low revenue ACO, as defined by § 425.20.

Based on our program experience, the inexperienced/experienced and low/high revenue ACO determination could be affected by changes in the ACO participant list that are made during the course of the agreement period, where the changes are not motivated by the ACO's desire to avoid program requirements regarding participation options. ACO participant list changes during the agreement period could affect the categorization of ACOs, particularly for ACOs close to the threshold percentage. We considered that an ACO may change its composition of ACO participants each performance year. Any approach under which we would apply different policies to ACOs based on a determination of ACO participant prior experience under performance-based risk would need to recognize the potential for an ACO to add or remove ACO participants which could affect whether an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives. We are concerned about the possibility that an ACO may be eligible to receive AIPs and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding these inexperience and low revenue eligibility requirements.

To identify and address these circumstances, we propose at § 425.316(e)(1) that CMS will monitor ACOs that receive AIPs to determine if they remain low revenue ACOs that are inexperienced with performance-based risk. We would monitor ACOs for changes in the risk experience of ACO participants that would cause an ACO to be considered experienced with performance-based risk or a high

revenue ACO and therefore ineligible for AIPs.

We propose at § 425.316(e)(2) to specify that if an ACO that receives AIPs and becomes experienced with performance-based risk Medicare ACO initiatives or becomes a high revenue ACO during any performance year of the agreement period, CMS will cease paying the ACO AIPs starting the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO and may take compliance action as specified in §§ 425.216 and 425.218.

Under proposed § 425.316(e)(3), the ACO would be obligated to repay spent and unspent AIPs if CMS takes pre-termination action under § 425.216 and the ACO continues to be experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to such compliance action (for example, the next deadline for updating the ACO participant list). To retain its AIP, an ACO that CMS determines to be experienced with performance-based risk or a high revenue ACO would be required to remedy the issue by the deadline specified by CMS. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list so that the ACO could meet the definition of a low revenue ACO. If the ACO fails to respond to compliance action under § 425.216 or otherwise fails to remedy the eligibility issue by the applicable deadline, the ACO would be required to repay all AIPs it had received. CMS will provide written notification to the ACO of the amount due, and the ACO must pay such amount no later than 90 days after the receipt of notification. CMS may recover the amount owed by reducing the amount of any shared savings.

To aid us in determining whether it would be appropriate for us to recoup AIP funds from an ACO, we further propose to update the definitions of ''inexperienced with performance-based risk Medicare ACO initiatives'' and ''experienced with performance-based risk Medicare ACO initiatives'' under § 425.20 to allow for a rolling lookback period of the 5 most recent performance years beginning from the current performance year being monitored. This would be applicable to both ongoing compliance determinations and the assessment of an ACO's application to participate under a participation option for an agreement period under proposed § 425.600(h). We provide ACOs with preliminary participation options reports throughout the application and ACO participant list change request cycles so ACOs can be fully informed of the impact of becoming experienced with performance-based risk or high revenue for the upcoming performance year.

(c) Termination of Advance Investment Payments

Under §§ 425.216 and 425.218, CMS can terminate an ACO or take pre-termination actions (such as requesting a corrective action plan) if CMS determines that an ACO is not in compliance with eligibility or other Shared Savings Program requirements. Accordingly, if we finalize our proposal to implement AIPs, CMS could take remedial action under those provisions if an ACO receiving such payments becomes experienced with performance-based risk Medicare ACO initiatives, becomes a high revenue ACO, spends AIPs for a prohibited use, fails to comply with other AIP requirements, or meets any of the grounds for ACO termination set forth in § 425.218(b). Where appropriate, we would work with the ACO to understand why the noncompliance with AIP requirements had occurred so that we could develop an effective plan of action and monitoring technique. However, our existing pre-termination actions do not include the cessation of payments to an ACO. To protect the Trust Funds, encourage speedy resolution of noncompliance, and provide an added safeguard against abuse, we propose at § 425.630(h) that CMS may terminate an ACO's receipt of AIPs if the ACO ceases to meet the eligibility requirements specified in proposed § 425.630(b)(3) and (4), fails to comply with other AIP requirements, or meets any of the grounds for termination set forth at § 425.218(b). For the same reasons, we further propose under § 425.630(h)(3) that CMS may immediately terminate an ACO's AIPs without taking any of the pre-termination actions set forth in § 425.216. We expect that immediate termination of AIPs would be invoked only in cases of serious noncompliance or when the ACO's actions or inaction poses a risk of harm to beneficiaries or negatively affects access to care.

(8) Recoupment

In AIM, we recouped prepaid shared savings from any shared savings earned by an ACO in its current agreement period, and if necessary, future agreement periods. If the ACO did not achieve shared savings, then the prepaid shared savings were not recouped. Additionally, the balance of funding was not recouped if the ACO completed the agreement period and decided not to reenroll in a second agreement period. If the ACO terminated prior to the end of its 3-year agreement period, the remaining balance was required to be repaid in full. During the model, we observed that offering new small ACOs prepaid shared savings that they were not at risk of being forced to repay if they did not achieve savings was a critical incentive for small providers and suppliers to form ACOs to join AIM and the Shared Savings Program. Based on our experience in AIM, we are proposing at § 425.630(g) a policy for recoupment of the AIPs from an ACO. The Shared Savings Program now has 5-year agreement periods instead of 3-year agreement periods that were in effect during AIM, so some timing adjustments to the recoupment policy are necessary, but the majority of the proposed policy aligns with AIM recoupment policy.

We are proposing at § 425.630(g)(1) to recoup AIPs from any shared savings, as defined in § 425.20, earned by the ACO in any performance year until CMS has recouped all AIPs. We further propose that if there are insufficient shared savings to recoup the AIPs made to an ACO for a performance year, we would carry forward that remaining balance owed to the subsequent performance year(s) in which the ACO achieves shared savings, including any performance year(s) in a subsequent agreement period.

Under new § 425.630(g)(2), we propose that in circumstances where the amount of shared savings earned by the ACO is revised upward by CMS for any reason, we would reduce the redetermined amount of shared savings by the amount of AIPs made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, we propose that the ACO would not receive a refund of any portion of the AIPs previously recouped or otherwise repaid.

We propose under § 425.630(g)(3) that for each performance year, we would not recoup an amount of AIPs greater than the shared savings earned by an ACO for that performance year. Thus, if an ACO does not earn shared savings in its agreement period or a renewed agreement period, we would not recoup any of the AIPs from the ACO.

For example, if an ACO received $300,000 in AIPs and achieved shared savings of $500,000 for the first performance year, we would recoup $300,000 and pay $200,000 in shared

savings to the ACO. Alternatively, if an ACO received $300,000 in AIPs and achieved shared savings of $200,000 for the first performance year, we would recoup only $200,000 and not pay any shared savings to the ACO. The outstanding balance of $100,000 would be carried forward, to be recouped in a future performance year in which the ACO achieves shared savings. Under a third scenario, if the ACO does not achieve shared savings in all 5 performance years of its agreement period and does not renew for another agreement period in the Shared Savings Program, we would not recoup any AIPs made to the ACO. However, to protect the program from abuse, CMS would recoup any outstanding balance from a re-entering ACO determined to be experienced with performance-based risk Medicare ACO initiatives. We note that a ''re-entering ACO,'' as defined at § 425.20, includes an ACO that is a new legal entity that is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years.

Under the new § 425.630(g)(4), we propose that if an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received. In such a case, CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. This proposal ensures that AIPs are used by ACOs that complete their agreement period and reduces the risk of ACOs using termination to avoid repayment of the AIPs.

As described in section III.G.2.a.(2) of this proposed rule, we have proposed that an ACO is not eligible for AIPs unless it is a low revenue ACO, as defined at § 425.20, and inexperienced with performance-based risk Medicare ACO initiatives, as defined at § 425.20. A goal of the AIPs is to encourage the formation of ACOs, and based on experience in AIM, we recognize that new, smaller ACOs need start-up funding to join the Shared Savings Program and to continue care coordination over the agreement period.

As described earlier in section III.G.2.a.(7).(b) of this proposed rule, we have proposed to monitor and notify ACOs if they become high revenue or experienced with performance-based risk during a performance year so they may choose to modify their ACO participant lists for the next performance year to maintain their low revenue and inexperienced status. Under our proposal at § 425.316(e), if CMS determines that an ACO is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, CMS will cease payment of AIPs starting the quarter after the ACO became experienced with performance-based risk or became a high revenue ACO, and CMS may take compliance action as specified in §§ 425.216 and 425.218. For example, if CMS determines that an ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO during the first performance year of the agreement period, CMS will not pay to the ACO additional AIPs, effective the next quarterly payment after the ACO became experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO, which would be January 1 of the second performance year. In addition, CMS could take compliance action as specified in §§ 425.216 and 425.218. If CMS determines after all AIPs have been paid (for example, during the third performance year of the agreement period) that an ACO became experienced with performance-based risk Medicare ACO initiatives, CMS may take compliance action as specified in § 425.216. For example, CMS could issue a request for a corrective action plan, and the ACO would be required to come back into compliance the following performance year. If an ACO remains noncompliant after the compliance deadline specified by CMS, we will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification. To achieve the goal of AIPs and ensure the payments support new, smaller ACOs, we are proposing at § 425.316(e) that if CMS determines during the agreement period in which an ACO received an AIP that the ACO became a high revenue ACO or became experienced with performance-based risk Medicare ACO initiatives, the ACO may be required to repay all AIPs it received during the agreement period. We propose to provide written notification to the ACO of the amount due and to require the ACO to pay such amount no later than 90 days after the receipt of notification.

We are proposing at § 425.630(g)(5) that if an ACO that received AIPs enters into proceedings relating to bankruptcy, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved. We propose that the notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). We propose that the notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices. This proposal is consistent with the AIM model participation agreement and ensures that CMS can recover AIPs if an ACO files for bankruptcy.

We are seeking comment on all aspects of our proposals for recoupment of the AIPs made to ACOs.

b. Smoothing the Transition to Performance-Based Risk

(1) Background

Since its inception in 2012, the Shared Savings Program has included both one-sided financial models (shared savings only) and two-sided financial models (shared savings and shared losses) for ACOs to select based on the arrangement that makes the most sense for their organization. Over the years, we have modified available financial models (participation options) providing ''on-ramps'' to attract both providers and suppliers that are new to value-based purchasing, as well as more experienced entities that are ready to accept two-sided risk. We have modified these participation options to adjust the maximum level of risk that must be assumed under two-sided models and to smooth the transition to two-sided models, including modifying eligibility criteria and adding flexibility for more advanced ACOs to transition to risk-based arrangements more quickly. These participation option modifications have been informed by lessons learned from CMS' experience with the program, testing through other initiatives conducted by the CMS Innovation Center under section 1115A of the Act (the Pioneer ACO Model, the Next Generation ACO Model and the Medicare ACO Track 1+ Model), and feedback from interested parties.

In the November 2011 final rule (76 FR 67904), we stated our belief that a one-sided model would have the potential to attract a large number of participants to the program and broadly

introduce value-based purchasing to providers and suppliers, many of whom may not have participated in a value-based purchasing initiative before. Another reason we included the option for a one-sided track with no downside risk was that this model would be accessible to and likely to attract small, rural, safety net, and physician-only ACOs. However, we also noted that while a one-sided model could provide incentives for participants to improve quality, it might not be sufficient incentive for participants to improve the efficiency and cost of healthcare delivery (76 FR 67904). Thus, in the November 2011 final rule, we created two tracks in which ACOs could choose to participate. The one-sided risk model (Track 1) incorporated the statutory payment methodology under section 1899(d) of the Act, and the two-sided model (Track 2) was also based on the payment methodology under section 1899(d) of the Act but incorporated performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models. Track 1 was available for an ACO's initial agreement period, and all ACOs were required to transition to Track 2 to continue participating in subsequent agreement periods. (76 FR 67904 through 670909).

In the June 2015 final rule (80 FR 32759), we reiterated our intent to continue to encourage ACOs' forward movement up the ramp from the one-sided model to performance-based risk. The June 2015 final rule discussed policy changes that would allow ACOs not yet ready to transition to performance-based risk a second agreement period under the one-sided model, while also encouraging ACOs to enter performance-based risk models by lowering the risk under the existing Track 2 and offering an additional two-sided model (Track 3) that was based on the payment methodology under Track 2 but incorporated different elements intended to make it more attractive for entities to accept increased performance-based risk. (80 FR 32759 through 32780).

In 2017, the Innovation Center designed an additional option for eligible Track 1 ACOs, referred to as the Track 1+ ACO Model, to facilitate ACOs' transition to performance-based risk. The Track 1+ ACO Model was a time-limited model that began on January 1, 2018; it was based on Shared Savings Program Track 1 but tested a payment design that incorporated more limited downside risk, as compared to Track 2 and Track 3. Our early experience with the design of the Track 1+ ACO Model demonstrated that the availability of a lower-risk, two-sided model is an effective way to encourage ACOs in one-sided models (including ACOs within a current agreement period, initial program entrants (that is, new ACO legal entities), and renewing ACOs to progress more rapidly to performance-based risk.

Most recently, in the December 2018 final rule (83 FR 67822), CMS redesigned the participation options available under the program to encourage ACOs to transition more rapidly to two-sided models under two tracks, a BASIC track and an ENHANCED track. Both tracks are designed for 5-year agreement periods. The BASIC track includes a glide path with 5 Levels (A through E) that allows eligible ACOs to begin under a one-sided model for 2 years (each year of which is identified as a separate level (Levels A and B)) and advance to a two-sided model that includes incrementally higher levels of risk and reward (Levels C, D, and E) for the remaining 3 years of the agreement period.[197] We allowed additional flexibility for new ACO legal entities that qualify as low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives to participate for up to 3 performance years under a one-sided model (4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) of the BASIC track's glide path before transitioning to the highest level of risk and potential reward under the BASIC track (Level E) for the final 2 years of the agreement period.

Based on a combination of factors, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track along with the number of agreement periods that the ACO may participate in the BASIC track. These factors include the degree to which the ACO's ACO participants control total Medicare Parts A and B fee-for-service (FFS) expenditures for the ACO's assigned beneficiaries (low revenue ACOs versus high revenue ACOs), and the ACO's experience and its ACO participants' experience with the Shared Savings Program and other performance-based risk Medicare ACO initiatives. As noted in the December 2018 final rule (83 FR 67826), these policies were designed to increase savings for the Medicare Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles.

An ACO's ability to participate in the BASIC track is limited, and all ACOs eventually must transition to participation in the ENHANCED track to continue in the program. High revenue ACOs are limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. Low revenue ACOs are limited to, at most, 2 agreement periods for a total of 10 performance years under the BASIC track (or 11 performance years in the case of an ACO that participates in an agreement period that began on July 1, 2019, and spans a total of 6 performance years). These agreement periods do not need to be sequential. The regulations at § 425.600(e) also require that should a low revenue ACO, identified as experienced with performance-based risk Medicare ACO initiatives, have changes in the revenue of its ACO participants that would cause the ACO to be considered a high revenue ACO (as these terms are defined in § 425.20) for a given performance year, the ACO must take corrective action or terminate its participation under the BASIC track by the end of the current performance year (83 FR 67877 and 67878).

As discussed in the December 2018 final rule (83 FR 67881), many commenters who addressed the proposed changes to the participation options disagreed with the more aggressive transition of ACOs to performance-based risk under the proposed program redesign. Some commenters cautioned that although the proposed requirement that all ACOs undertake two-sided risk at some point during their first agreement period might improve the performance of the ACOs that continue to participate in the Shared Savings Program, it might also reduce ACO participation in the program. Several commenters expressed concern that the change in program requirements might cause ACOs to end their participation in the Shared Savings Program and create a barrier to entry for ACOs to join the program. One commenter recommended that CMS carefully monitor Shared Savings Program participation and change course if participation falls precipitously. As discussed in the Regulatory Impact Analysis section below, AIM participants—a subset of Track 1 ACOs that meaningfully outperformed peer ACOs in reducing spending and earning shared savings over the period from 2016 through 2018—dropped out at an elevated frequency before even attempting to enter the one-sided model (upside-only)

[197] For more information on shared savings and shared losses for each level, see Shared Savings Program Participation Options for Performance Year 2022, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ssp-aco-participation-options.pdf.*

portion of the BASIC track glide path, where spending reductions were found to be similar regardless of an AIM ACO's decision to continue or exit the program.[198] This suggests both that, while an upside-only participation option with a lower shared savings rate can be a highly effective incentive for smaller, low-revenue ACOs targeted by AIM, such ACOs also likely feel a correspondingly-magnified disincentive to accept exposure to even the limited downside risk presented by the current BASIC track glide path, and not even superior performance under Track 1 appears to provide enough confidence for such ACOs to consistently move into participation options leading to assumption of two-sided risk.

Several commenters expressed concern that requiring the rapid assumption of significant levels of risk by ACOs would discourage new participants and impede current ACOs' ability to make patient-centered infrastructure investments that are necessary for successful participation. Another commenter believed that reducing the amount of time permitted under the one-sided model was ill-advised and would jeopardize ACOs' continued participation. Our response to these comments included our commitment to continue to monitor program participation and consider further refinements to the program's participation options as we gained experience with implementing the redesigned program (83 FR 67835).

Most commenters on the proposed participation options that were finalized in the December 2018 final rule recommended that CMS extend the time any ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years proposed for ACOs eligible to participate under the BASIC track with participation agreements beginning on or after January 1, 2020 that do not qualify for a third year under the one-sided model under the exception in § 425.600(a)(4)(i)(B)(2)(*ii*), stating that it takes longer than 2 performance years to implement meaningful changes in a healthcare delivery model and among healthcare provider and patient populations. Other commenters believed that the progression to two-sided risk that we proposed and ultimately finalized was far too aggressive and would deter participation. These commenters generally suggested allowing for 4 or 5 performance years (or a full agreement period) under a one-sided model. Some commenters suggested that rural ACOs should be allowed at least two, 5-year agreement periods under a one-sided model (83 FR 67847). At the time of the December 2018 final rule, we disagreed with suggestions to allow ACOs to remain under the one-sided model for an extended time because our experience suggested that the availability of 6 performance years of one-sided risk under Track 1 and the ability to benefit from significant waivers available in the program could be leading to the formation of one-sided ACOs that were not making serious efforts to improve quality and reduce spending, potentially crowding out the formation of more effective ACOs.

The design of the current Shared Savings Program participation options, including a BASIC track glide path incorporating more limited downside risk as compared to the ENHANCED track, demonstrates that the availability of a lower-risk, two-sided model is an effective way to encourage ACOs (including ACOs within a current agreement period, initial program entrants, re-entering ACOs, and renewing ACOs) to progress more rapidly to performance-based risk. For PY 2022, a majority of the 483 ACOs (284 (59 percent)) that currently participate in the Shared Savings Program, selected a two-sided model. Refer to Table 43.

TABLE 43: 2022 Shared Savings Program ACO Track Information

ACO Track	ACOs	Percent
One Sided (41% of ACOs)		
BASIC Track Levels A&B	199	41%
Two Sided (59% of ACOs)		
BASIC Track Levels C&D	40	8%
BASIC Track Level E*	98	21%
ENHANCED Track*	146	30%
TOTAL ACOs PY 2022	483	100%

*Qualifies as an Advanced Alternative Payment Model (APM).

Note: Tracks 1, 2, 3 and the Track 1+ ACO Model are no longer applicable as of PY 2022.

While many ACOs have agreed to participate under a two-sided model, not all ACOs appear to be ready to take on performance-based risk. In 2020 and 2021, due to the PHE for COVID-19, as defined in § 400.200, we provided additional participation option flexibilities, allowing ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement and ''freeze'' their participation for PY 2021 and PY 2022 at their PY 2020 and 2021 levels, respectively. (See May 2020 Interim Final Rule with comment period (IFC) (85 FR 27575 and 27576), CY 2021 PFS final rule (85 FR 84767 through 84769), and CY 2022 Hospital Inpatient Prospective Payment Systems final rule (86 FR 45502 through 45506)). Thus, eligible ACOs may have elected to remain in the same level of the BASIC track's glide path in which they participated during PY 2020 and PY 2021 once again, for PY 2022. As specified in the fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) / Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45503 through 45506), for PY 2023, an ACO that elected one or both of these advancement deferral options will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if the ACO had advanced automatically to the required level of the BASIC track's glide path for PY 2021 and PY 2022, as applicable (unless the ACO elects to advance more quickly before the start of PY 2023). For ACOs that continued their participation in the Shared Savings Program into the next performance year, when given the

[198] Trombley, M.J., et al. ACO Investment Model Produced Savings, But the Majority of Participants Exited when Faced with Downside Risk. *Health Affairs*. 2020; 138–146. doi:10.1377/hlthaff.2020.01819.

opportunity to freeze at the ACO's current BASIC track level on the glide path, most eligible ACOs under a one-side model (Level A or Level B) chose to remain in a one-sided model:

- 140/157 (89 percent) currently participating ACOs chose to maintain their participation in a one-sided model rather than move to risk for PY 2021.
- 103/140 (74 percent) chose to maintain their participation in a one-sided model rather than move to risk for PY 2022.

As we have addressed several times through previous rulemakings, an ongoing consideration for CMS is how long ACOs should be allowed to participate under a one-sided model. We have to balance our goal of driving the greatest possible shift to high-value care delivery, which we believe may be incentivized most effectively under a two-sided model, with concern that requiring ACOs to take on too much downside risk too quickly will disincentivize program participation and reduce the program's potential to positively affect the quality and cost of care furnished to beneficiaries. Although we continue to believe there are stronger incentives for increased efficiency when ACOs are in a two-sided risk track, ACOs continue to report that they are constrained by the current participation options and need more time to invest in infrastructure and redesigned care processes for high quality and efficient health care service delivery before transitioning to performance-based risk. Additionally, some ACOs have reported that the ENHANCED track is too risky, and therefore, requiring ACOs to eventually move to ENHANCED may hinder continued participation. Therefore, we believe it would be prudent to provide greater flexibility for ACOs to join the program under one-sided risk and to remain in the program under lower levels of performance-based risk in order to balance our desire to see more ACOs participate under performance-based risk while also working towards our goal of increasing overall Shared Savings Program participation and improving outcomes for beneficiaries, including high need beneficiaries with complex health and social needs who may most benefit from ACOs' linked networks of clinicians with incentives, to close inequitable gaps in care associated with poorer health outcomes.[199] [200]

We note that the Shared Savings Program was established as, and remains, a voluntary program for providers and suppliers that choose to participate in an ACO and to become accountable for the quality and cost of care for an assigned population of Medicare FFS beneficiaries. Thus, to promote the program's goal of ACO accountability for the quality and cost of care furnished to assigned beneficiaries, we believe it would be appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model (with a lower sharing rate) for a longer period of time, rather than risk having those ACOs leave the program altogether to avoid transitioning to two-sided risk before the ACO is confident it has been able to implement the systemic changes necessary to deliver high quality, value-based care. Even if an ACO does not earn shared savings, ACOs have demonstrated that they are likely saving Trust Fund dollars by modifying their ACO participants' behavior to coordinate care and carry out other interventions to improve quality and financial performance. In particular, ACOs with average to above-average baseline spending may decide that a benchmark with a neutral or negative regional adjustment presents too much exposure to performance-based risk if they are also required to participate under a two-sided model, but they may otherwise elect to participate and begin to reduce spending if permitted to join and remain under a one-sided model.

In light of these considerations, we are concerned that our current policy of considering an ACO's status as a high- or low revenue ACO (as these terms are defined in § 425.20) in determining the participation options available to the ACO may disincentivize certain providers and suppliers from forming ACOs or joining existing ACOs. At the start of July 1, 2019, 52 percent of the participating ACOs met the definition of ''high revenue ACO.'' For PY 2020, 48 percent of participating ACOs were high revenue ACOs, for PY 2021, 46 percent of participating ACOs were high revenue ACOs, and for PY 2022, 44 percent of participating ACOs are high revenue. In all, the share of participating ACOs that meet the definition of high revenue ACO has decreased by 8 percentage points over three participation years in a consistent downward trajectory.

It is not our intent to incentivize ACOs to exclude high cost providers and suppliers from their ACO participant lists to avoid meeting the definition of high-revenue ACO. We believe participation in the Shared Savings Program encourages providers and suppliers to provide better coordinated, more efficient care for beneficiaries and results in savings for the Trust Funds. High revenue ACOs, which typically include hospitals as ACO participants, have a greater opportunity to control assigned beneficiaries' total Medicare Parts A and B FFS expenditures, as they coordinate a larger portion of the assigned beneficiaries' care across care settings (83 FR 41916 through 41918). As a result, we believe it is important to provide participation options that will encourage more providers and suppliers, including those with high revenues, to participate in the Shared Savings Program.

In addition, given the feedback we have received from ACOs and other interested parties, as well as our observation of trends in ACO participation, we believe ACOs inexperienced with performance-based risk Medicare ACO initiatives, regardless of their status as a high- or low revenue ACO, may be more likely to participate in the program if they are allowed more time under a one-sided model than is currently allowed under the available participation options. As discussed in the December 2018 final rule, some commenters opposed limiting high revenue ACOs to one agreement period in the BASIC track. Given that high revenue ACOs are responsible for a greater share of Medicare Part A and Part B FFS spending than low revenue ACOs, one commenter agreed that it is reasonable to ask high revenue ACOs to assume greater levels of risk and/or at a faster pace than low revenue ACOs. But this commenter also suggested that CMS should take into account that larger health systems must invest in change across a much broader delivery ≥footprint≥ and so may require additional investments over multiple years to make transformative system changes, and also need a longer time to recoup investments (such as in the form of shared savings). Similarly, we heard from at least one interested party that high revenue ACOs need more of an on-ramp to meaningful levels of two-sided risk because there are bigger systemic policies in place that take time to modify in order to create changes within the organization that focus on providing value-based care.

[199] McWilliams JM, Landon BE, Chernew ME, Zaslavsky AM. Changes in patients' experiences in Medicare accountable care organizations. *N Engl Med. 2014;371(18):1715–1724. doi:10.1056/NEJMsa1406552.*

[200] Seshamani M, Jacobs DB. Leveraging Medicare to Advance Health Equity. *JAMA.* 2022;327(18):1757–1758. doi:10.1001/jama.2022.6613.

As noted above in section G.2.a.(2), CMS has outlined a renewed vision and strategy for how the Innovation Center will drive health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries. Further, in a January 2022 article, CMS stated our goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[201] The Shared Savings Program is the largest Medicare alternative payment model with 483 ACOs participating in PY 2022 and 11 million assigned beneficiaries.[202] As a result, the Shared Savings Program will play an important role in achieving the goal of creating care relationships with accountability for quality and costs for all Medicare FFS beneficiaries.

We believe APMs are well positioned to close gaps in health equity. Under the Shared Savings Program, ACOs are incentivized to provide high quality care while reducing unnecessary duplication of services and preventing medical errors. We believe it is important to encourage providers and suppliers who are providing care to high needs beneficiaries to join and/or form ACOs to help close gaps in health equity. We also believe flexibility with respect to the timeline for progression to two-sided risk is important in the Shared Savings Program to encourage small, rural, safety-net providers to form ACOs or to join larger, more urban practices to share resources. Both of these strategies can be utilized to help provide high need beneficiaries served by small, rural, safety-net providers with the resources to better coordinate their care and improve outcomes.

(2) Proposal for a 5-Year Agreement Period Under a One-Sided Model for Eligible ACOs

We are proposing to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Shared Savings Program. While the proposal for currently participating ACOs to elect to maintain their participation at Level A or Level B for the remainder of their current agreement period would apply beginning January 1, 2023, we are proposing to make all other policies outlined in this section effective for agreement periods starting on or after January 1, 2024, rather than January 1, 2023, because the majority of the application cycle for the 2023 performance year will occur before this rule is finalized. Establishing a January 1, 2024 start date for these changes would allow ACOs time to understand the scope of the proposed changes more fully before making decisions related to their participation, and would allow CMS adequate time to update its processes and application-related guidance documents for the new participation options, if they are finalized.

First, we propose to add a new § 425.600(a)(4)(i)(C)(*3*) to allow an ACO that enters the BASIC track's glide path at Level A under § 425.600(a)(4)(i)(A)(*1*) and is currently at Level A to elect to remain in Level A under § 425.600(a)(4)(i)(A)(*1*) for all subsequent performance years of the agreement period, for agreement periods beginning on or after January 1, 2024. Per the newly proposed § 425.600(a)(4)(i)(C)(3)(*i*), in order to be eligible to participate under Level A of the BASIC track for subsequent years of the agreement period as described in § 425.600(a)(4)(i)(C)(*3*), an ACO must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track under § 425.600(a)(4), and is not participating in an agreement period under the BASIC track as a renewing ACO (as defined in § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under § 425.600(a)(4); and the ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20). We propose to extend this participation option to re-entering former Track 1 ACOs, because they have not previously participated in the BASIC track glide path and we would like to encourage them to begin participating in the program again. Eligibility for this participation option would not consider the ACO's revenue status.

For eligible ACOs, prior to the automatic advancement of the ACO to Level B, the ACO could elect to remain in Level A for all subsequent performance years of the agreement period. Under the new § 425.600(a)(4)(i)(C)(3)(*ii*), we propose to require that this voluntary election by an ACO to remain in Level A for the entirety of its first agreement period be made in the form and manner and by a deadline established by CMS. In the case of an ACO that elects to remain in Level A for the entirety of its first agreement period, the ACO generally would be eligible to enter into a subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years of one-sided risk. If an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have 7 years under one-sided risk, whereas a new ACO entering under the BASIC track's glide path may be eligible for as few as 2 performance years under one-sided risk under the current participation options. We believe that allowing a maximum of 7 years under one-sided risk would strike a more appropriate balance within the current structure of 5 performance year agreement periods and the BASIC track glide path, which provides for 2 years under the one-sided model. Currently, ACOs inexperienced with performance-based risk Medicare ACO initiatives generally are limited to 2 years under a one-sided model, which ACOs have informed us is not enough time before transitioning to risk. We believe giving ACOs longer than the proposed 7 years or potentially unlimited time under a one-sided model would dilute the program's ability to meaningfully influence expenditures and quality through the incentives provided by ACO risk assumption. This proposed change to extend the time eligible ACOs may remain under a one-sided model would allow ACOs more time to make investments in care improvement and to capitalize on those investments, while still working to lower costs and improve care quality for their assigned beneficiaries.

Although we are proposing to increase the potential time certain ACOs may spend in one-sided risk, our proposal includes a pathway to transition these ACOs into two-sided risk. We continue to recognize that ACOs are best able to select their participation options to meet the needs of their organizations, including when to time their transition to performance-based risk, including within an agreement period. We propose to add a new § 425.600(g)(1)(i) to provide that an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 performance years and a second time in progression on the glide path). Furthermore, the ability to enter a

[201] Seshamani, M., Fowler E., Brooks-LaSure C. et al. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.22* January. doi:10.1377/forefront.20220110.198444.

[202] See Medicare Shared Savings Program Fast Facts (January 2022), available at *https://www.cms.gov/files/document/2022-shared-savings-program-fast-facts.pdf.*

second agreement period in the BASIC track's glide path would be limited by the proposed new § 425.600(g)(1)(ii), which would provide that an ACO that enters an agreement at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following: The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time. In new paragraph (g)(1)(iii), we propose that an ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track. For example, an ACO that voluntarily terminates its participation agreement during its first agreement under Level A of the BASIC track's glide path and chooses to re-enter the BASIC track under the proposed new § 425.600(g)(1)(ii) would be re-entering a second agreement and, if continuing to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives, could progress along the BASIC track glide path for this second agreement period. For its third agreement, the ACO would be required to enter the BASIC track at Level E for all years of the agreement period, or the ENHANCED track. These provisions would prevent ACOs from terminating their participation agreement before transitioning to two-sided risk in order to stay under the one-sided model, potentially indefinitely.

We also propose to add a new § 425.600(a)(4)(i)(B)(2)(*vi*) to allow currently participating ACOs that are participating in the BASIC track at Level A or Level B for performance year 2022 to elect to continue in their current level of the BASIC track glide path for performance year 2023 and continuing for the remainder of the agreement period. If the ACO does not elect to remain under Level A or Level B, for performance year 2023, the ACO would be automatically advanced to the next level of the BASIC track's glide path to which the ACO would have automatically advanced absent any election to maintain its participation level for performance year 2022 and, if applicable, the election to maintain its participation level for performance year 2021 under § 425.600(a)(4)(i)(B)(2)(*iii*), unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). We propose to modify § 425.600(a)(4)(i)(B)(2)(*iv*) to account for the proposed new election option under paragraph (*vi*). We also propose to add a new § 425.600(a)(4)(i)(B)(2)(*vii*) to extend this participation option to eligible ACOs that begin an agreement period in Level A or Level B on January 1, 2023.

We recognize we are proposing to implement participation option changes in the middle of an agreement period for currently participating ACOs in the BASIC track Level A or Level B. However, we are proposing to allow these ACOs to elect to remain at the level in which they are currently participating for PY 2022 for the remainder of their current agreement period, and to offer a similar option to ACOs that enter an agreement period starting under Level A or Level B of the BASIC track glide path beginning on January 1, 2023, because we wish to encourage continuity of participation in the program and do not see any advantage to excluding currently participating ACOs and ACOs with participation agreements beginning on January 1, 2023, from the same participation option that we are proposing to make available to newly participating ACOs inexperienced with performance-based risk Medicare ACO initiatives that begin a new agreement period on or after January 1, 2024. We propose that, in the case of a currently participating ACO that elects to remain in Level A or Level B under proposed § 425.600(a)(4)(i)(B)(2)(*vi*) or (*vii*) for the remainder of its current agreement period, the ACO would be eligible to enter into a subsequent agreement period under the BASIC track's glide path pursuant to § 425.600(g)(1)(ii), giving the ACO an opportunity to participate for up to 2 additional years under one-sided risk. For performance year 3 of this subsequent agreement period, the ACO would be automatically advanced to Level C and to each successive level of risk and potential reward for each performance year thereafter, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). We propose to require that this voluntary election by an ACO to remain in one-sided risk in Level A or Level B for the remainder of its current agreement period be made in the form and manner and by a deadline established by CMS.

Consistent with our proposal to expand the participation options for renewing and re-entering ACOs, we propose to make changes to the definition of *Performance-based risk Medicare ACO initiative* in § 425.20 and to the regulation at § 425.224(a)(4) to allow a renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path (Level A or B) to reapply for participation in the BASIC track's glide path, provided the ACO is not identified as having also participated previously under a two-sided model. The proposed change to the definition of *Performance-based risk Medicare ACO initiative* in § 425.20 would be effective for performance years beginning on January 1, 2023 and for subsequent years. Specifically, we propose to amend paragraph (1)(i) of the definition of *Performance-based risk Medicare ACO initiative* in § 425.20 to include only Levels C through E of the BASIC track, and to remove the one-sided Levels A and B from the definition. Similarly, in § 425.224(a)(4), we propose to remove the reference to ''a one-sided model of the BASIC track's glide path (Level A or Level B),'' so that renewing and re-entering ACOs that previously participated in a one-sided model of the BASIC track's glide path but that are not identified as having participated in a two-sided model, are not limited to reapplying for participation in a two-sided model.

We recognize that the annual application and change request cycle will begin before the CY 2023 PFS final rule is issued. Accordingly, we will give ACOs currently participating in Level A or B of the BASIC track glide path the opportunity during the change request cycle to indicate whether they are interested in maintaining their participation at Level A or Level B under this proposed policy, should it be finalized. ACOs expressing such an interest would not be required to submit a repayment mechanism at that time. In the event this proposed policy is not finalized in the CY 2023 PFS final rule, ACOs that are required under § 425.600(a)(4)(i)(B)(*2*) to advance from Level A or Level B to a two-sided risk model for PY 2023 would have a limited opportunity to submit a repayment mechanism, resolve any deficiencies, and have it approved in time for the

start of the performance year. ACOs that fail to establish a repayment mechanism that complies with the requirements of § 425.204(f) by the deadline specified by CMS would be terminated as required under § 425.600(a)(4)(i)(B)(*3*).

In order to determine an ACO's eligibility to participate under the proposed new participation options, we are proposing to consider an ACO's experience with performance-based Medicare ACO initiatives only, rather than also considering the ACO's status as a high- or low revenue ACO. Our proposal would make the ENHANCED track optional for all ACOs, regardless of experience with performance-based risk Medicare ACO initiatives. As discussed above, because we do not wish to disincentivize the formation of ACOs that include high-cost providers (that is, high revenue ACOs), we propose not to use revenue status for determining ACO participation options. This proposal also would simplify the determination of which participation options are available to a particular ACO and would reduce burden on ACOs (in terms of ascertaining likely available participation options) and CMS (in terms of determining ACO eligibility for its selected participation option). We propose to modify the regulations in § 425.600(a)(4)(i)(B), § 425.600(d), and § 425.600(e) to apply only to agreement periods beginning on or after July 1, 2019, and before January 1, 2024, because these complex provisions depend on the ACO's status as a high- or low revenue ACO. For agreement periods beginning on or after January 1, 2024, we propose to streamline the specification of the BASIC track glide path in § 425.600(a)(4)(i)(C) and eligibility for participation options in § 425.600(g), which would define an ACO's participation options based solely on the ACO's level of experience with performance-based risk Medicare ACO initiatives.

We believe that the determination of whether an ACO is inexperienced or experienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20) could be affected by changes made by an ACO to its ACO participant list during the course of an agreement period, particularly for ACOs that are determined to be inexperienced when their agreement period begins but are close to the threshold percentage of forty percent of ACO participants having participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the agreement start date. Any approach under which we would apply different policies to ACOs based on the prior experience of an ACO's ACO participants with performance-based risk Medicare ACO initiatives would need to recognize the potential for an ACO to add or remove ACO participants during the course of the agreement period, which could affect whether the ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives. We are concerned about the possibility that an ACO may begin participating under a one-sided, shared savings-only level of the BASIC track based on a determination that the ACO is inexperienced with performance-based risk Medicare ACO initiatives, and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding the limitations under our proposed participation options regarding the availability of the one-sided model for experienced ACOs.

To protect against this circumstance, we propose adding a new provision at § 425.600(h), which would provide that for performance years beginning on or after January 1, 2024, CMS will monitor ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to a voluntary election under § 425.600(a)(4)(i)(B)(*2*)(*vi*), (a)(4)(i)(B)(*2*)(*vii*), or (a)(4)(i)(C)(*3*) for changes to their ACO participant list that would cause an ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

We further propose to update the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives under § 425.20 to allow for a rolling lookback period (applicable to both the assessment of an ACO's application to participate under a participation option for an agreement period and to ongoing compliance determinations under proposed § 425.600(h)) of the 5 most recent performance years beginning from the current performance year being monitored. If an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (as specified in § 425.20), we propose under the new provision at § 425.600(h)(2)(i) that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year. As specified under the proposed new provision at § 425.600(h)(2)(ii), the ACO would be required to meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b), in accordance with § 425.600(a)(4)(i)(B)(*2*)(*v*) or § 425.600(a)(4)(i)(C)(*4*), as applicable. If the ACO fails to meet the requirements to participate under performance-based risk, its agreement would be terminated in accordance with § 425.600(a)(4)(i)(B)(*3*) or § 425.600(a)(4)(i)(C)(*5*), as applicable.

An eligible ACO that enters a new agreement period beginning on or after January 1, 2024, at Level A of the BASIC track would be permitted to elect to remain in Level A for the next performance year and remain at Level A for all subsequent performance years of the agreement period under the proposed new provision at § 425.600(a)(4)(i)(C)(*3*). We would review the ACO's proposed ACO participant list for each subsequent performance year and provide feedback to allow the ACO to assess if the proposed changes to its ACO participant list (if any) would yield a determination that the ACO qualifies as experienced with performance-based risk Medicare ACO initiatives based on the 5 most recent performance years prior to the performance year under review (for example, PY 2020 through PY 2024, if PY 2025 were under review). CMS would perform the same monitoring activity ahead of all subsequent performance years of the agreement period in which the ACO elected to remain in Level A under the proposed new provision at § 425.600(a)(4)(i)(C)(*3*).

If the ACO were to meet the definition of experienced with performance-based risk Medicare ACO initiatives based on the proposed ACO participant list for the performance year under review, the ACO would still be permitted to complete that performance year in Level A of the BASIC track. CMS would then reassess the proposed ACO participant list for the subsequent performance year. If at that point the ACO has made changes to its ACO participant list such that it no longer meets the definition of experienced with performance-based risk Medicare ACO initiatives, the ACO would be permitted to complete that

subsequent performance year in Level A of the BASIC track. But if the ACO continues to meet the definition of performance-based risk Medicare ACO initiatives based on its proposed ACO participant list for the subsequent performance year, the ACO would be automatically advanced to Level E of the BASIC track for that performance year, provided the ACO met all requirements to participate under performance-based risk. If the ACO did not meet all requirements to participate under performance-based risk, including establishment of an adequate repayment mechanism and selection of an available MSR/MLR, the ACO's participation agreement would be terminated.

This proposed policy is illustrated in Table 44. There, hypothetical ACOs A and B begin a Shared Savings Program agreement period on January 1, 2024, and are determined for that performance year to be inexperienced with performance-based risk Medicare ACO initiatives. Both ACOs are monitored ahead of PY 2025 as proposed, and both continue to meet the definition of inexperience with performance-based risk Medicare ACO initiatives based on their proposed ACO participant lists for PY 2025. Consistent with their status as inexperienced with performance-based risk Medicare ACO initiatives, both ACO A and ACO B elect to maintain their participation at level A of the BASIC track for all years of the agreement period, as proposed in § 425.600(a)(4)(i)(C)(*3*). Ahead of PY 2026, both ACOs are determined to be experienced with performance-based risk Medicare ACO initiatives based on their proposed ACO participant lists for PY 2026. Both ACOs are permitted to remain at Level A of the BASIC track for PY 2026, but will continue to be monitored by CMS. Ahead of PY 2027, the proposed ACO participant list for ACO A for PY 2027 is reviewed and the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, and ACO A is thus permitted to continue its agreement under Level A of the BASIC track for PY 2027. However, ACO B is determined to continue to meet the definition of experienced with performance-based risk Medicare ACO initiatives based on its proposed ACO participant list for PY 2027, and therefore is advanced to Level E of the BASIC track for PY 2027 and must remain there for the remainder of its agreement period.

TABLE 44: Monitoring of Risk Experience for Agreement Periods under Level A of the BASIC Track

Performance Year for which Proposed ACO Participant List is Monitored	ACO A		ACO B	
	Risk Experience Determination	Level of the BASIC Track	Risk Experience Determination	Level of the BASIC Track
PY 2024	Inexperienced	A	Inexperienced	A
PY 2025	Inexperienced	A	Inexperienced	A
PY 2026	Experienced	A	Experienced	A
PY 2027	Inexperienced	A	Experienced	E
PY 2028	Inexperienced	A	Experienced	E

Our intention with the policies proposed in this section is to provide ACOs with a more gradual on-ramp to taking on two-sided risk and to allow them the flexibility they need to best ensure their readiness to take on two-sided risk. We believe our proposals would encourage more ACOs to form and join the program as well as encourage currently participating ACOs to remain in the program. Additionally, we believe our proposals would help to increase our participation options so that an ACO has more flexibility to select the option that best fits its circumstances when applying to participate in the Shared Savings Program.

Increasing the participation options in the program by expanding the flexibilities for participation in the one-sided model would also be expected to promote health equity for underserved and vulnerable beneficiaries by providing ACOs and their ACO participants with an additional opportunity to close gaps in care for underserved populations before they are required to transition to performance-based risk. These additional flexibilities would also afford ACOs that serve high need beneficiaries or face greater start-up costs with more time to prepare to take on two-sided risk, as well as allowing ACOs to balance their response to the COVID–19 pandemic, while also managing normal operations, implementing care redesigns and improving the quality of care provided to beneficiaries.

We seek comment on the foregoing proposals for ACO participation options in the Shared Savings Program.

We also seek comment on whether to extend the proposed option for certain ACOs inexperienced with performance-based risk Medicare ACO initiatives to spend an entire five-year agreement period under the one-sided model of the BASIC track for an additional agreement period for low revenue ACOs that enter the BASIC track as a new legal entity (that has never before participated in the Shared Savings Program and is not identified as a renewing or re-entering ACO), so that these ACOs would be eligible for a second one-sided only agreement period followed by a third agreement period in the BASIC track glide path, which would include an additional 2 years under the one-sided model (for a total of 12 years under the one-sided model) before progressing to two-sided risk. We are considering extending this participation option only to low revenue ACOs that enter the BASIC track as a new legal entity because other ACOs have already had time under one-sided risk and therefore do not need a second agreement period in one-sided only. Although, as we noted previously, using revenue status in determining the participation options available to ACOs may disincentivize certain providers and suppliers from forming ACOs or joining existing ACOs, we have observed that there are differences in financial performance outcomes based on revenue status. An independent study found the first three entry cohorts of physician-group ACOs

(ACOs whose core medical groups for beneficiary attribution were not associated with hospitals, which are generally low revenue) consistently reduced spending as their first agreement periods progressed such that average per beneficiary benefit spending was reduced by $300 in 2015 compared to only $37 lower for hospital-integrated ACOs (ACOs whose core medical groups for beneficiary attribution were part of larger organizations or health systems that included hospitals).[203] We therefore estimate that this alternative could increase program retention for the type of ACO that, as a group, has demonstrated greater program savings under an upside-only incentive in the past (that is, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives) and increase program savings (net of shared savings payments) by at least $1 billion.

Under this alternative, a voluntary election by a qualifying ACO to remain in Level A for the entirety of its second agreement period in the BASIC track would be made in the form and manner and by a deadline established by CMS. In the case of a qualifying ACO that elects to remain in Level A for the entirety of its second agreement period in the BASIC track that is determined to be low revenue at the time of application for renewal to a third agreement period in the BASIC track, the ACO generally would be eligible to enter into this subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years of one-sided risk. If an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have a total of 12 years under one-sided risk in the BASIC track.

If we were to adopt this alternative, we are concerned about the possibility that an ACO may be found eligible to continue for a full second agreement period under a one-sided model of the BASIC track because of a determination that it is an inexperienced, low revenue ACO at the time of application, and then quickly thereafter seek to add experienced and/or higher-revenue ACO participants, thereby avoiding the requirement under our proposed participation options to move to the glide path for the second agreement period under the BASIC track if it did not meet the eligibility requirements to continue under the one-sided model for the entire agreement period. To protect against these circumstances, we would continue monitoring for experience with performance-based risk Medicare ACO initiatives. Thus, we would establish a monitoring policy to monitor for changes to revenue status during the ACO's second agreement period in the one-sided only model of the BASIC track, to ensure that the ACO continues to meet the definition of a low revenue ACO (as well as an ACO inexperienced with performance-based risk Medicare ACO initiatives). We would take the following approach to ensuring continued compliance of ACOs with the eligibility requirements for this alternative participation option. When an ACO applies for a second agreement period entirely under the one-sided model of the BASIC track, we would determine whether the ACO would be a high- or low revenue ACO (and an ACO inexperienced or experienced with performance-based risk Medicare ACO initiatives) as defined under § 425.20, using the ACO's ACO participant list for the first performance year of the new agreement period. Only low revenue ACOs would be eligible to elect this participation option to remain in Level A for the entirety of their second agreement period under the BASIC track, and we would continue to monitor for revenue status (as well as experience with performance-based risk Medicare ACO initiatives) during the second agreement period. If, during the second agreement period, the ACO began to meet the definition of a high revenue ACO (or an ACO experienced with performance-based risk Medicare ACO initiatives), we propose that the ACO would be permitted to complete the remainder of its current performance year under Level A, but the ACO would be ineligible to continue participation in Level A after the end of that performance year unless it took corrective action. For example, if the ACO participants' total Medicare Parts A and B FFS revenue increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list, so that the ACO could continue to meet the definition of low revenue ACO. In the event the ACO does not take steps to maintain its status as a low revenue ACO, we would take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, to ensure the ACO did not continue in Level A for subsequent performance years of the agreement period. For example, we would send the ACO a request for a corrective action plan to resolve their change in revenue status, which would allow the ACO time to modify its ACO participant list or PECOS enrollment data such that the ACO could continue to meet the definition of a low revenue ACO. If the ACO continued to meet the definition of a high-revenue ACO at the end of the next performance year (that is, based on the ACO's proposed ACO participant list for the following performance year), we propose that the ACO would be required to move to the level of the BASIC track's glide path in which the ACO would be participating for the following performance year if it had begun the agreement period in the BASIC track's glide path instead of under the one-sided model-only path. This includes meeting the applicable requirements prior to entering performance-based risk, such as establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b). Under this alternative, if an ACO remains either high revenue or experienced with performance-based risk Medicare ACO initiatives based on the ACO's proposed ACO participant list for the following performance year, the ACO would be required to move to Level E, as discussed in the earlier proposal for monitoring for changes in risk experience.

When the ACO applies for a third agreement period under the BASIC track, we would determine revenue status at the time of application. Only low revenue ACOs that continued to be inexperienced with performance-based risk Medicare ACO initiatives and had entered into a participation agreement under the BASIC track only twice would be eligible to enter the BASIC track glide path. If at time of application CMS determined the ACO was a high revenue ACO as defined under § 425.20 (or if the ACO met the definition of experienced with performance-based risk Medicare ACO initiatives), then it would be required to participate in Level E of the BASIC track (or the ENHANCED track) for the agreement period, rather than entering the BASIC track glide path. If at any time during the ACO's third agreement period CMS determined the ACO had begun to meet the definition of a high revenue ACO (or of an ACO experienced with performance-based risk Medicare ACO initiatives), the ACO would be permitted to complete the remainder of the current performance year under the ACO's current level of the glide path, but would be ineligible to continue participation in the glide path after the end of that performance

[203] McWilliams JM, et al. Medicare Spending After 3 Years of the Medicare Shared Savings Program. *New England Journal of Medicine.* Sept. 2018. 379: 1139–1149. DOI: 10.1056/NEJMsa1803388.

year and would be moved to Level E of the BASIC track unless the ACO took corrective action to modify its ACO participant list as described above.

(3) Proposal To Remove the Limitation on the Number of Agreement Periods an ACO Can Participate in Level E of the BASIC Track

Currently, there are limitations on how long ACOs may participate in the BASIC track, including at Level E, the BASIC track's highest level of risk and potential reward. Under § 425.600(d)(1)(ii), high revenue ACOs experienced with performance-based risk Medicare ACO initiatives may not participate in the BASIC track at all unless they meet the limited criteria in § 425.600(d)(1)(ii)(B). Under § 425.600(d)(2)(ii), low revenue ACOs experienced with performance-based risk Medicare ACO initiatives may enter the program under the BASIC track Level E and remain in the BASIC track at that level for up to 2 agreement periods. Under § 425.600(d)(3), low revenue ACOs may participate under the BASIC track for a maximum of 2 agreement periods, after which they must move to the ENHANCED track to continue participating in the program. A low revenue ACO may only participate in the BASIC track for a second agreement period if it satisfies either of the following: (i) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time; or (ii) for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track only one time.

Some ACOs have reported that they would rather leave the program than be required to move to the ENHANCED track and have requested that CMS make the ENHANCED track optional for ACOs. In our implementation of the Shared Savings Program, we intend to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for Medicare FFS beneficiaries. As discussed above, we continuously seek, based on experience and feedback, to balance creating sufficient incentives for participation in a voluntary program, with ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds. Accordingly, we now believe it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under the BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track. Our experience shows that ACOs in the BASIC Track Level E and ACOs in the ENHANCED Track have similar performance results. Therefore, we propose to add a new § 425.600(g)(2) to specify that if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter BASIC track Level E under § 425.600(a)(4)(i)(A)(*5*) for all performance years of the agreement period, or the ENHANCED track under § 425.600(a)(3). These options would be available without regard to the ACO's status as a high- or low revenue ACO. We also propose that all ACOs would be permitted to participate indefinitely under the BASIC track, Level E, or the ENHANCED track. This would include ACOs currently in the ENHANCED track or that participate under the ENHANCED track in the future. These ACOs would be permitted to enter a new participation agreement under Level E of the BASIC track. We believe it is important to offer this option to encourage ACOs that believe they may be ready to take on the higher level of risk and potential reward under the ENHANCED track to progress to that participation option, secure in the knowledge that the more moderate level of risk and potential reward under Level E of the BASIC track would be available to the ACO in the future if the ACO concludes based on experience that that participation option is more appropriate for the ACO than the ENHANCED track. We anticipate providing education and offering outreach to ACOs on the available participation options through various methods available, including ACO Coordinators, guidance documents, tip sheets, FAQs, and a bi-weekly newsletter to assist ACOs as they navigate to higher levels of risk and potential reward throughout their participation in the program.

In conjunction with these proposed changes to the participation options available under the program, we are proposing to make several technical and conforming changes to the existing regulations. We propose to modify § 425.600(a)(4)(ii) to reference the new paragraph § 425.600(g)(2) in addition to the currently identified paragraph (d). We propose to add new § 425.605(b)(2)(ii)(E) to include a provision for an ACO to select its MSR/MLR if it automatically transitions from Level A to Level E of the BASIC track's glide path under the new § 425.600(h)(2). Lastly, we propose to modify § 425.605(d)(1) and (d)(2) to reference the new paragraph § 425.600(g) in addition to the current reference to § 425.600(d).

We invite comments on all proposals described in this section III.G.2. of this proposed rule, and related issues, including the alternative approach under which we would permit low revenue ACOs to remain in a one-sided only model of the BASIC Track for a second agreement period before entering the BASIC Track glide path in their third agreement. Please refer to Table 45, which summarizes the participation option policies we are proposing, and to Table 46, which summarizes the alternative participation option policy.

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TABLE 45: Proposed Participation Options

ACO type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation Options		
		First Agreement Period (or Subsequent for Renewing/Re-entering ACOs, or Current for Currently Participating ACOs)	Next Agreement Period	Future Agreement Periods
New legal entity (An ACO that has never participated in the Shared Savings Program and is not identified as a re-entering ACO or a renewing ACO)	Inexperienced*	A, A, A, A, A via one-time election prior to the start of the second performance year	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
New legal entity (An ACO that has never participated in the Shared Savings Program and is not identified as a re-entering ACO or a renewing ACO)	Experienced	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Inexperienced– former BASIC track Level A or B	A, B, C, D, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Inexperienced* – former Track 1	A, A, A, A, A via one-time election prior to the start of the second performance year	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
Re-entering ACO	Experienced – participated under Track 2, 3, BASIC track Level C, D, or E, ENHANCED track, the Track 1+ ACO Model, or another performance-based risk ACO initiative	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Currently participating ACO in Level A or B for PY 2022	Inexperienced* – BASIC track Level A or B	Current level (remain at A or B for remainder of current agreement period)	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
ACOs in Level A or B with agreement periods beginning on January 1, 2023	Inexperienced* – BASIC track Level A or B	Current level (remain at A or B for remainder of current agreement period)	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track
Renewing ACO	Inexperienced	A, B, C, D, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track
Renewing ACO	Experienced – participated under Track 2, 3, BASIC track Level C, D, or E, or ENHANCED track, the Track 1+ ACO Model, or another performance-based risk ACO initiative	E, E, E, E, E	E, E, E, E, E	Remain in Level E indefinitely, or move to ENHANCED track

Any ACO, regardless of type or experience level, may elect to progress more quickly along the BASIC track glide path or to apply to enter a new agreement period under the ENHANCED track at any time.

*Under the newly proposed § 425.600(h), if an inexperienced ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (as specified in § 425.20), that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year.

TABLE 46: Alternative Participation Option

ACO type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	ACO low or high revenue	Participation Options			
			First Agreement Period	Second Agreement Period	Third Agreement Period	Future Agreement Periods
New legal entity (An ACO that has never participated in the Shared Savings Program and is not identified as a re-entering ACO or a renewing ACO)	Inexperienced*	Low revenue	A, A, A, A, A via one-time election prior to the start of the second performance year of the first agreement period	A, A, A, A, A via one-time election prior to the start of the second performance year of the second agreement period	A, B, C, D, E	Remain in Level E indefinitely, or move to ENHANCED track

Any ACO, regardless of type or experience level, may elect to progress more quickly along the BASIC track glide path or to apply to enter a new agreement period under the ENHANCED track at any time.
*Under the newly proposed § 425.600(h), if an inexperienced ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (as specified in § 425.20), that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year.

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3. Determining Beneficiary Assignment Under the Shared Savings Program

a. Proposed Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

For the performance year beginning on January 1, 2022, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(vi) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

(A) CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(9) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(10) 99439 (code for non-complex chronic care management).

(11) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(12) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(13) 99495 and 99496 (codes for transitional care management services).

(14) 99497 and 99498 (codes for advance care planning; services

identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in ETA hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 and G2252 (codes for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(13) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) Proposed Revisions

(a) HCPCS and CPT Codes Used in Assignment

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we are proposing to recognize for payment starting in CY 2023, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years in order to remain consistent with billing and coding guidance under the PFS.

We propose to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Prolonged services HCPCS codes GXXX2 and GXXX3, if finalized; and (2) Chronic Pain Management HCPCS codes GYYY1 and GYYY2, if finalized. The following provides additional information about the HCPCS codes that we are proposing to add to the definition of primary care services used in assignment:

- *Prolonged Services Codes GXXX2 and GXXX3:* In section II.F of this proposed rule, we are proposing that prolonged nursing facility services furnished by a physician or non-physician practitioner (NPP) would be reportable under GXXX2, which would be used when the total time for the primary service is exceeded by 15 or more minutes to account for the additional time spent. The long descriptor would be GXXX2 *(Prolonged nursing facility* evaluation and management *service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility* evaluation and management *services*). (*Do not report GXXX2 on* the same *date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report GXXX2 for any time unit less than 15 minutes)).* Prolonged physician or NPP nursing facility (NF) services would be reportable once 95 minutes are spent for initial NF visits, and once 85 minutes are spent for subsequent NF visits, and for each additional 15 minutes furnished thereafter. Because GXXX2 would be reportable for each additional 15-minute increment of time beyond the total time for CPT codes 99306 and 99310, which are included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe GXXX2 should also be included in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for the code is made permanent through the CY 2023 PFS rulemaking, since this code would represent the provision of services that are already included in the definition of primary care services for a longer period of time.

We are additionally proposing that prolonged home or residence services by a physician or NPP would be reportable under GXXX3 *(Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report GXXX3 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report GXXX3 for any time unit less than 15 minutes)).* Because code GXXX3 would be reportable as an add-on code to CPT codes 99345 or 99350 once the practitioner spends 15+ minutes beyond the total time finalized for the primary service, and CPT codes 99345 and 99350 are included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe GXXX3 should also be included in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for the code is made permanent through the CY 2023 PFS rulemaking, since this code would represent the provision of services that are already included in the definition of primary care services for a longer period of time.

- *Chronic Pain Management (CPM) HCPCS codes GYYY1 and GYYY2:* In section II.E this proposed rule, we are proposing two new HCPCS codes for CPM services, beginning January 1, 2023. We recognize that there is no existing code that specifically describes the work of the clinician involved in performing the tasks necessary to perform holistic, CPM under current Medicare payment policy. These new HCPCS codes would be analogous to Chronic Care Management (CCM) services and Principal Care Management (PCM) services because GYYY1 would include similar care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional, as described in CPT code 99424; and GYYY2 would include similar activities as described in CPT code 99425, both of which already are included in the Shared Savings Program definition of primary care services used in assignment. Additionally, we expect that most of these services would be

billed by primary care practitioners who are focused on long-term management of their patients with chronic pain and we expect the billing practitioner to demonstrate in the Medicare patient's record when there is coordination or continuity of care between a specialist or other relevant practitioner, such as a physical therapist or occupational therapist, which we believe supports the inclusion of the services described by these HCPCS codes in our definition of primary care services for purposes of beneficiary assignment under the Shared Savings Program. Under the Shared Savings Program, CCM services reported using CPT codes 99437, 99439, 99487, 99489, 99490 and 99491 and HCPCS code G2058 and PCM services reported using CPT Codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065 currently are included in the definition of primary care services for purposes of beneficiary assignment (refer to 85 FR 84749 and 86 FR 65274 through 65275) and as such, to remain consistent with updates to the scope of care management services payable under the PFS, we are proposing to include these CPM services codes, if finalized, in the definition of primary care services used for beneficiary assignment. Accordingly, we propose to include HCPCS code GYYY1 *(Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1 30 minutes must be met or exceeded.))* and GYYY2 *(Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). When using GYYY2 15 minutes must be met or exceeded.)* because GYYY2 is similar in scope as GYYY1, just for additional duration, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2023, and subsequent performance years, if payment for these codes is made permanent through the CY 2023 PFS rulemaking. Refer to other sections of this proposed rule for detailed, technical discussion regarding the proposed description, payment, and utilization of these HCPCS and CPT codes.

(b) Technical Update to the Description of CPT Codes 99341 through 99350

In the CY 2019 PFS final rule (83 FR 60093), we updated our regulations at § 400(c)(1)(iv)(A)(4) by adding the descriptor ''codes for evaluation and management services furnished in a patients' [sic] home for claims identified by place of service modifier 12'' to CPT codes 99341 through 99350, as used in the definition of primary care services used in assignment for performance years (or a performance period) starting during 2019 and performance year 2020. This descriptor, slightly modified to correct a typographical error, also applied for the performance year starting on January 1, 2021, under § 425.400(c)(1)(v)(A)(5) and continues to apply for the performance year starting on January 1, 2022, and subsequent performance years, under § 425.400(c)(1)(vi)(A)(5).

On March 17, 2021, the AMA updated the CPT® Editorial summary of Panel Actions for February 2021 (*https://www.ama-assn.org/system/files/2021-03/february-2021-summary-panel-actions.pdf*). This summary describes revisions made to Home and Residence Services to revise the guidelines for CPT codes 99341 through 99350 to include services provided in assisted living facilities, group homes, custodial care facilities, and residential substance use treatment facilities. As discussed in section II.C of this proposed rule, we are proposing to adopt these changes under Medicare Fee for Service payment policies and as such, we are proposing conforming changes to omit the reference to ''for claims identified by place of service modifier 12'' from the description for CPT codes 99341 through 99350. This proposed modification would be reflected in the proposed definition of primary care services used in assignment for the performance year starting on January 1, 2023, and subsequent performance years, in a new provision of the regulations at § 425.400(c)(1)(vii)(A)(*7*).

In this proposed provision, CPT codes 99341 through 99350 would be described as codes for evaluation and management services furnished in a patient's home, without the place of service 12 identifier. The place of service logic is included in claims processing algorithms and therefore accounted for in paid claims used by the Shared Savings Program in determining beneficiary assignment. As described in Medicare Claims Processing Manual, Publication 100–04, Chapter 26, place of service codes are two-digit codes placed on health care professional claims to indicate the setting in which a service was provided. Claims submitted for services that are allowable when provided in certain settings will process only when the appropriate place of service is included on the claim. Place of service 12 is defined as ''location, other than a hospital or other facility, where the patient receives care in a private residence.'' In previous rulemaking, we updated the reference to CPT codes 99341 through 99350 in the definition of primary care services at § 425.400(c) to include place of service 12 for clarity; however, we now believe it is no longer accurate as these codes have been revised to include multiple places of service, any of which we would consider to be the patient's home.

(c) Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA) of 2021, was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals that were CAHs or rural hospitals with not more than 50 beds, participating in Medicare, as of the date of enactment of the CAA, are eligible to seek conversion to an REH. REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas. Section 1861(kkk)(1)(A) of the Act defines the term ''REH services'' as emergency department and observation services, as well as other medical and health services furnished on an outpatient basis as specified by the Secretary

Under section 1861(k)(10) of the Act, payments will be made for REH services

furnished on or after January 1, 2023. We expect that REHs will submit claims in a similar manner to hospital outpatient departments paid under the OPPS. As a result, we do not believe that we need to propose special policies regarding the treatment of services furnished in REHs for purposes of beneficiary assignment under the Shared Savings Program. Rather, we would consider services furnished in REHs in the same manner that we currently consider services furnished in hospital outpatient departments for purposes of conducting assignment under the Shared Savings Program. However, we will continue to monitor the development of payment policy for REHs to determine whether any adjustments to our assignment policies may be necessary to account for services furnished in REHs and will consider whether any findings may warrant changes through future notice and comment rulemaking. In addition, we note that in section III.G.3.b. of this proposed rule, we are proposing to include on an ACO's ACO provider/supplier list any CCNs that may be deactivated and then reactivated, or disenrolled as one facility type but re-enrolled as another facility type, which would include any CAHs that elect to re-enroll as rural emergency hospitals.

We propose to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vi) along with the proposed additional HCPCS codes GXXX2 and GXXX3, and GYYY1 and GYYY2, if these additional codes are finalized through the CY 2023 PFS rulemaking. We further propose to omit from the description for CPT codes 99341 through 99350, the reference to ''for claims identified by place of service modifier 12.'' We propose that the new provision at § 425.400(c)(1)(vii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years. Further, we propose technical modifications to the introductory text in § 425.400(c)(1)(vi) to limit the applicability of this provision to the performance year starting on January 1, 2022.

We seek comment on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2023, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

b. Proposal on Identifying how CMS Certification Numbers Will Be Included and Used in Beneficiary Assignment

(1) Background

Under the Shared Savings Program, ACOs are accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries that are assigned to the ACO (§ 425.100(a)). ACOs are formed by one or more ''ACO participants,'' which are responsible for managing and coordinating care for the assigned beneficiary population. The Shared Savings Program regulations define ''ACO participant'' at § 425.20 as an entity identified by a Medicare-enrolled billing Taxpayer Identification Number (TIN) through which one or more ''ACO providers/suppliers'' bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118 (herein ''ACO participant list''). An ''ACO provider/supplier'' is an individual or entity that: (1) is a provider (as defined at § 400.202) or supplier (as defined at § 400.202); (2) is enrolled in Medicare; (3) bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers that is required under § 425.118 (herein ''ACO provider/supplier list''). CMS requires each ACO to execute contractual agreements with each of its ACO participants (''ACO participant agreements''), to ensure that the ACO participant and each ACO provider/supplier billing through the TIN of the ACO participant agree to the requirements of the Shared Savings Program.

Under § 425.118(a), an ACO must maintain, update, and submit to CMS an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its National Provider Identifier (NPI), CCN, or other identifier). All Medicare-enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of an ACO participant must be included on the ACO provider/supplier list (§ 425.118(a)(4)).

(a) Development and Maintenance of the ACO Participant List

An ACO must submit a draft ACO participant list before the start of an agreement period and before each performance year thereafter. CMS reviews the draft list, conducts a program integrity screening on the individuals and entities identified on the list, approves or rejects each entry on the list, and informs the ACO of the contents of the resulting ACO participant list. In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO participant list before the start of its agreement period and before each performance year thereafter.

An ACO must maintain and periodically update its ACO participant list. An ACO is required to notify CMS no later than 30 days after an entity ceases to be an ACO participant. The entity is deleted from the ACO participant list as of the termination date of the entity's ACO participant agreement. Absent unusual circumstances, the ACO participant's data will continue to be utilized for certain operational purposes. CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, or the obligation of the ACO to report on behalf of eligible clinicians who bill under the TIN of an ACO participant for certain CMS quality initiatives, to reflect the deletion of entities from the ACO participant list that become effective during the performance year.

If the ACO wishes to add an entity to its ACO participant list, it must submit a request to CMS. If CMS approves the request, the addition becomes effective on January 1 of the next performance year. ACO participants may not be added during a performance year.

The ACO participant list is critical to Shared Savings Program operations. CMS uses the ACO participant list to identify which entities are in the ACO, generate the ACO provider/supplier list, determine which Medicare FFS beneficiaries will be assigned to an ACO, establish the historical benchmark, perform financial calculations, and coordinate among CMS quality reporting initiatives.

(b) Development and Maintenance of the ACO Provider/Supplier List

In accordance with § 425.118, ACOs must submit to CMS before the start of an agreement period and before each performance year thereafter an accurate and complete list identifying each ACO provider/supplier (including its NPI,

CCN, or other identifier). In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO provider/supplier list. In addition, ACOs are required to notify CMS of any changes in their ACO provider/supplier list in accordance with § 425.118(c). Specifically, an ACO must notify CMS within 30 days after an individual or entity becomes or ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant (§ 425.118(c)).

For performance years starting on January 1, 2019, and subsequent performance years, CMS creates the initial ACO provider/supplier list for a performance year by using the Provider Enrollment, Chain, and Ownership System (PECOS) to identify by CCN and NPI all of the providers and suppliers, respectively, that have reassigned their right to receive Medicare payment to the TIN of an ACO participant. As with its ACO participant list, each ACO must review that initial list, make any necessary corrections, and certify the resulting ACO provider/supplier list prior to the start of a performance year and at such other times as specified by CMS.

(c) Use of Lists in Beneficiary Assignment

For performance years 2012 through 2018, ACOs were required to identify on their ACO participant list the CCNs for certain provider types (FQHCs, RHCs, Electing Teaching Amendment (ETA) hospitals, and Method II Critical Access Hospitals (CAHs)) as well as the ACO participant TIN under which the CCN was enrolled in Medicare. CMS required ACOs to identify CCNs and their associated TIN information because otherwise it would not be possible to identify the institutional claims billed by those providers for purposes of beneficiary assignment since TINs are not retained in the CMS Integrated Data Repository (IDR) for the claims submitted by FQHCs, RHCs, ETA hospitals, and Method II CAHs.

Additionally, ACOs that included FQHCs and/or RHCs on their ACO participant list were also required to identify, through an attestation, a list of physicians who directly provided primary care services in each FQHC or RHC (herein ''attestation list'') in accordance with § 425.404(a). The linkage of the physicians to the FQHCs and RHCs provided via the attestation list was necessary because physicians and other individual practitioners cannot reassign their Medicare billing rights to an FQHC or RHC CCN. Therefore, although FQHCs, RHCs, physicians, and other individual practitioners are all listed in PECOS, the PECOS reassignment data used to generate the ACO provider/supplier list could not have linked the NPI of a physician or other practitioner to the CCN of an FQHC or RHC and, in turn, to an ACO participant TIN. This attestation list was collected through the ACO's application to the Shared Savings Program and could be updated annually with changes, if any, which would take effect January 1 of the next performance year.

In accordance with § 425.404(b), for performance years starting on January 1, 2019, and subsequent years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim, identified using the CCN as a unique identifier for an individual FQHC/RHC, as a primary care service performed by a primary care physician. For performance years starting on January 1, 2019, and subsequent performance years, CMS uses PECOS to identify the CCN or NPI of each ACO provider/supplier enrolled under an ACO participant TIN. Specifically, CMS uses PECOS data to identify the following: (i) all Medicare enrolled entities (as identified by a CCN) that have enrolled under the TIN of an ACO participant; and (ii) all individual practitioners (as identified by an NPI) who have reassigned their right to receive Medicare payment to the TIN of an ACO participant. The resulting initial ACO provider/supplier list reflects PECOS enrollment information at a single point in time. An ACO may need to add or remove a provider or supplier who has reassigned his or her right to receive Medicare payment to the TIN of an ACO participant after the ACO certified its ACO provider/supplier list for the performance year. An ACO that needs to make a change to its certified ACO provider/supplier list must notify CMS within 30 days of the change.

For purposes of beneficiary assignment, we identify claims for services furnished by Method II CAHs, ETA hospitals, FQHCs, and RHCs using the CCN assigned to the facility. In general, ACO participants are identified by TINs. However, the TINs for Method II CAHs, FQHCs, RHCs, and ETA hospitals are not included in the National Claims History and IDR claims files, so we use the CCN as the unique identifier to identify services furnished by these entities. Thus, for these providers, we use TINs from the certified ACO participant list and the associated CCNs sourced from PECOS as the basis for beneficiary assignment. We also use claims from participant TINs on the certified ACO participant list and the CCNs from the initial ACO provider/supplier list in the determination of whether an ACO is a high revenue ACO or low revenue ACO, as defined at § 425.20, and in the determination of beneficiary assignment upon which benchmark and performance year expenditure calculations are determined.

This approach allows CMS to identify ACO participant TINs and associated CCNs for the downstream operations necessary to prepare for the start of the performance year on January 1, including producing the ACO's list of prospectively assigned or preliminarily prospectively assigned beneficiaries, as applicable, at the start of each performance year.

Although the CCNs enrolled under a TIN may change during the course of an ACO's performance year, CMS' current operational process identifies any related CCN changes, through use of PECOS, only during the application process or the annual change request cycle. As with the certified ACO participant list, the CCNs used for purposes of beneficiary assignment and other operations are those that appear on the initial ACO provider/supplier list that is developed before the start of a performance year, and those CCNs remain applicable for the duration of the performance year. Any new CCNs that are established during a performance year are not used for purposes of beneficiary assignment and other operations until the start of the next performance year. The same applies to CCNs that become deactivated or change their TIN affiliation (that is, enroll under a different TIN) in PECOS during a performance year; those changes are not reflected in beneficiary assignment and other operations until the start of the next performance year. In PECOS, a ''deactivated'' enrollment status includes providers or suppliers whose Medicare billing privileges have been deactivated under § 424.540 as well as providers and suppliers that have voluntarily terminated their enrollment.

(2) Proposed Revisions

In order to administer the Shared Savings Program, we need to accurately identify all ACO participant TINs and ACO providers/suppliers that participate in the program. An accurate identification of the ACO participants and the CCNs that are ACO providers/suppliers in an ACO is critical for assignment of beneficiaries to the ACO, as well as for assessing the quality of care provided by the ACO to its

assigned beneficiaries. An accurate identification of the individuals and entities participating in the ACO is also critical for ensuring compliance with program rules and equally important for the ACO and its own operational and compliance purposes. Thus, both CMS and the ACO need to have a common understanding of the individuals and entities that compose the ACO. We obtain this common understanding by requiring per § 425.118 that the ACO certify the accuracy of its ACO participant and ACO provider/supplier lists prior to the start of each performance year. In addition, we require the ACO to notify CMS of any changes to its ACO participant list and ACO provider/supplier list throughout the performance year. Because we rely on these lists for operational purposes, we must have a transparent process that results in the accurate identification of all ACO participants and ACO providers/suppliers, including CCNs, that compose each ACO in the Shared Savings Program.

Based on our operational experience, we have determined that our current process, wherein we use an ACO's certified ACO participant list and data from PECOS to generate the initial ACO provider/supplier list prior to the start of the performance year and to identify the CCNs used for purposes of beneficiary assignment and other operations, may not capture all changes to providers and suppliers that participate in an ACO during the performance year. Specifically, our current processes do not capture: (a) new CCNs that are enrolled in Medicare under ACO participant TINs after the initial ACO provider/supplier list for a performance year is generated; or (b) CCNs that are in a deactivated status as listed in PECOS at the time the initial ACO provider/supplier list for a performance year is generated.

A CCN enrollment can become active or be deactivated in PECOS at any time, and a CCN can change TIN affiliations over time, including during the course of an ACO's performance year. Developing the initial ACO provider/supplier list, including the CCNs used for purposes of beneficiary assignment and other operations, before the start of a new performance year, and having that list remain applicable for the duration of the performance year, prevents us from later capturing during the performance year any newly-enrolled CCNs affiliated with ACO participant TINs.

Not recognizing new CCNs that enroll under an ACO participant TIN after the initial ACO provider/supplier list is generated impacts the determination of beneficiary assignment, expenditure and revenue calculations, and coordination among CMS quality reporting initiatives. Analysis based on PY 2019, 2019A, 2020, and 2021 data has shown that considering only the CCNs on the ACO provider/supplier list that is established prior to the start of the performance year, has a significant impact on assignment for some ACOs that include FQHCs, RHCs, ETA hospitals, and Method II CAHs. We found that 555 CCNs newly enrolled or re-enrolled during the course of PY 2020. CCNs were added across 143 (28 percent) of the 517 participating ACOs. Among the 344 ACOs under preliminary prospective assignment with retrospective reconciliation, 96 ACOs (28 percent) would have been impacted if the newly-enrolled CCNs were added to the ACO's ACO provider/supplier list during the 2020 performance year. An estimated 42,000 additional beneficiaries could have been assigned based on primary care services provided by CCNs enrolled during the performance year. Over 80 percent (that is, approximately 28,000) of these additional beneficiaries would have been concentrated among 12 ACOs under preliminary prospective assignment with retrospective reconciliation.

Accordingly, we propose to add a new provision at § 425.402(f) to reflect how CCNs are used in assignment. Under proposed § 425.402(f)(1), we state that prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status. Under proposed § 425.402(f)(2), we would use those CCNs in determining assignment for the performance year.

Under § 425.402(f)(3), we set forth how we would account for changes in CCN enrollment status during a performance year. Under our proposal, CCNs that enroll under an ACO participant TIN during the performance year would be reflected in program operations, including but not limited to: beneficiary assignment and revenue and expenditure calculations performed quarterly and during financial reconciliation for ACOs under preliminary prospective assignment with retrospective reconciliation. Specifically, if a new CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS would consider services furnished by that CCN in determining assignment to the ACO for the applicable performance year if the ACO has selected preliminary prospective assignment with retrospective reconciliation. We believe it is important to limit these updates to newly-enrolled CCNs during the performance year in order to ensure equivalency between historical benchmark expenditures and performance year expenditures. We propose to codify this change in the regulations at § 425.402(f)(3)(i).

We further propose that services furnished by a CCN with a deactivated enrollment status prior to that CCN becoming deactivated that is enrolled under the TIN of an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year. For purposes of this policy, we would use PECOS data to determine whether a CCN has a deactivated enrollment status. In the case of a CCN with a deactivated enrollment status that had multiple TIN affiliations prior to its deactivation, we propose to use the TIN with which the CCN was most recently enrolled to identify the appropriate ACO participant, if any, to which services furnished by the CCN should be attributed. We believe that the inclusion of CCNs with a deactivated enrollment status in PECOS is consistent with our policy on the consideration of claims billed by merged/acquired TINs as discussed in the June 2015 Final Rule (80 FR 32715). We believe that our rationale for the merged/acquired TIN policy also applies to CCNs with a deactivated enrollment status—namely, that (a) it is likely that the physicians and other practitioners furnishing primary care services billed via the CCN will continue to serve the same patient population that they served before the CCN deactivated its enrollment and (b) their patients may appear on the ACO's list of assigned beneficiaries at the end of the performance year. We believe this proposed change is important to maintain accuracy and comparability with regard to historical benchmark and performance year expenditure calculations. We propose to codify this change in the regulations at § 425.402(f)(3)(ii).

The policy under proposed § 425.402(f)(3)(ii) would apply to CCNs that are deactivated but later reactivated, or that are disenrolled as one facility type but later re-enrolled as another type of ACO provider/supplier. For example, if a CCN for a Method II

CAH was deactivated during PY 2022 and later re-enrolled as another facility type during PY2023, the services furnished by the deactivated CCN would be considered in determining the ACO's assigned beneficiary population and historical benchmark expenditures for PY 2023, which is not the case under current policy. Similarly, if a CCN for a Method II CAH was deactivated during PY 2022 and later re-enrolled as an REH with a new CCN in CY 2023, the services furnished by the deactivated CCN would be considered in determining the ACO's assigned beneficiary population and historical benchmark expenditures for PY 2023, which is not the case under current policy. By considering both the deactivated CCN and the new REH CCN in determining the ACO's assigned beneficiary population, we would ensure parity between historical benchmark expenditures and performance year expenditures.

We note that while we are proposing a specific policy to include deactivated CCNs in assignment, a similar policy is not needed for deactivated NPIs. During the performance and benchmark years, deactivated NPIs are included in assignment by default if they are included on a claim during the applicable assignment window.

We believe it is necessary to continue our current operational process, to not allow CCNs to switch between ACOs during the performance year. That is, if a CCN that was enrolled under the TIN of one ACO participant enrolls under a different TIN during a performance year, we would continue to treat services billed by the CCN as services furnished by the original ACO participant TIN under which the CCN was enrolled. We believe it is most appropriate to continue our current process and operationally treat CCNs in a similar fashion to ACO participant TINs and not allow a CCN to switch between ACOs during the performance year, rather than treating them in a similar fashion to an NPI that would be allowed to switch between ACOs during a performance year due to the relative magnitude of services provided by and assignment associated with a CCN, as compared to a much smaller amount of services and assignment associated with a single NPI, as described above. This operational approach would limit the potential for large impacts on performance year expenditure calculations and reduce the potential for gaming opportunities. Including services billed by the CCN as services furnished by the ACO participant is consistent with our policy on the treatment of ACO participant TINs included on the ACO participant list, wherein an entity is deleted from the ACO participant list as of the termination of its ACO participant agreement but claims billed under the ACO participant TIN continue to be included in program operations until the end of the performance year. We propose to codify this approach for CCNs in the regulations at § 425.402(f)(3)(iii).

We propose to identify all CCNs associated with ACO participant TINs as determined by the methodology described in the preceding paragraphs for use in assignment and other operations prior to determining historical benchmarks, running quarterly assignment, and financial reconciliation. We also intend to develop a mechanism for reporting to ACOs all CCNs used in assignment and for purposes of program operations to provide for a transparent process. This CCN information would be provided to ACOs on a periodic basis for informational purposes, and this information will not need to be certified by the ACO.

We propose that this revised approach to the treatment of CCNs would be applicable for purposes of all program operations for the performance year starting on January 1, 2023, and subsequent performance years. We seek comment on all aspects of this proposal.

4. Quality Performance Standard and Reporting

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59707 through 59715 respectively).

b. Revising the Shared Savings Program Quality Performance Standard

As discussed in this section of this proposed rule, we are proposing to further refine the quality performance standard for performance year 2023 and subsequent performance years through a combination of modifications. Specifically, we are concerned that the current structure of the quality performance standard creates a cliff of ''all-or-nothing'' scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum sharing rate for the applicable performance year. We propose to adopt an alternative quality performance standard that incorporates a sliding scale to avoid this cliff. This flexibility would be even more important as ACOs transition to eCQM/MIPS CQM reporting and when the quality performance standard under the Shared Saving Program increases to the 40th percentile across all MIPS Quality performance category scores starting in performance year 2024. Additionally, we are proposing to modify our approach for determining shared losses for ACOs in the ENHANCED track that would allow more ACOs to receive a shared loss rate based on a sliding scale rather than automatically being subject to the maximum loss rate of 75 percent. We are not proposing to change the current requirements for ACOs to be eligible to share in savings at the maximum sharing rate.

Second, we are proposing to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option.

Third, we are proposing to establish a health equity adjustment that would upwardly adjust an ACO's quality performance score when it delivers high quality care to underserved populations in order to support those ACOs serving a high proportion of underserved individuals, while also encouraging all ACOs to treat underserved populations.

We conclude the discussion with a summary of the proposals within this section of this proposed rule.

(1) Current Policy

In the CY 2021 PFS final rule, we finalized new Shared Savings Program quality reporting requirements that align with the Alternative Payment Model (APM) Performance Pathway (APP) under the Quality Payment Program and

revised the quality performance standard under the Shared Savings Program for performance years beginning on or after January 1, 2021, to reduce reporting burden and focus on patient outcomes. We also finalized a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. Specifically, for performance years 2021 and 2022, an ACO would be required to achieve a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores to be eligible to share in any savings generated, and for 2023 and subsequent performance years, an ACO would be required to achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores to be eligible to share in savings (85 FR 84719 through 84736).

We also finalized modifications to the Shared Savings Program regulations on the use of ACO quality performance in determining shared savings and shared losses (85 FR 84736 through 84740). We explained that section 1899(d)(1)(A) of the Act specifies that an ACO is eligible to receive a shared savings payment for a portion of the savings generated for Medicare, provided that the ACO meets both the quality performance standards established by the Secretary and achieves the required level of savings against its historical benchmark. Section 1899(d)(2) of the Act authorizes payments of shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary (according to section 1899(b)(3) of the Act) and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO, may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. Section 1899(d)(2) of the Act also requires the Secretary to establish limits on the total amount of shared savings paid to an ACO. We have also incorporated performance-based risk in the form of shared losses into certain financial models under the Shared Savings Program using the authority under section 1899(i)(3) of the Act to use other payment models.

In the CY 2021 PFS final rule, we finalized an approach to incorporating ACO quality performance in determining shared savings that would allow ACOs to maximize the potential shared savings they could earn across the Shared Savings Program's financial models. Specifically, we replaced the previous sliding scale approach with an all-or-nothing approach to determining shared savings based on quality performance (85 FR 84735).[204] Thus, under the current regulations, for performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the quality performance standard established under § 425.512, the ACO will share in any savings generated at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. If the ACO fails to meet the quality performance standard, the ACO will be ineligible to share in savings. Further, we finalized an approach that continued to allow CMS to take into consideration an ACO's quality performance score in calculating the amount of shared losses for certain two-sided models (85 FR 84740).[205] We finalized the following approach to determining the shared loss rate for ACOs participating in the ENHANCED track for performance years beginning on or after January 1, 2021, as specified under § 425.610(f)(2). If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the sharing rate of 75 percent under the ENHANCED track.
- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. The shared loss rate may not exceed 75 percent and may not be less than 40 percent. If the ACO fails to meet the quality performance standard, the shared loss rate will be 75 percent.

In the CY 2022 PFS final rule, we finalized an extended phase-in of the modified quality performance standard under the Shared Savings Program. Specifically, we extended the phase-in of the quality performance standard for an additional performance year (30th percentile for performance years 2021, 2022, and 2023). We also finalized that, for performance years 2022 and 2023, ACOs choosing to report on the 3 eCQMs/MIPS CQMs (meeting data completeness and case minimum requirements for all 3 measures) would meet the quality performance standard if they achieve a Quality performance category score equivalent to or higher than the 10th percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP measure set and achieve a Quality performance category score equivalent to or higher than the 30th percentile of the performance benchmark on at least 1 of the remaining 5 measures in the APP measure set (86 FR 65253 through 65272).

In summary, pursuant to the policies finalized in the CY 2022 PFS final rule (86 FR 65266 through 65270), a Shared Savings Program ACO, with the exception of an ACO in the first performance year of its first agreement period, will be eligible to share in savings at the maximum sharing rate if it:

- For performance year 2023:

++ Achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ If the ACO reports the three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set. Consequently, the ACO would be required to meet the performance benchmark on either 2 outcome measures (one measure at the 10th percentile and the other at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th

[204] We finalized modifications to the regulations to reflect this approach for Track 1 (under § 425.604), Levels A through E of the BASIC track (under § 425.605), Track 2 (under § 425.606), and the ENHANCED track (under § 425.610). The modifications to the regulations under § 425.604(d) governing the determination of the final sharing rate for Track 1 ACOs also applied to Track 1+ Model ACOs (85 FR 84763). We note that participation in Track 1, Track 2 and the Track 1+ Model concluded at the end of performance year 2021.

[205] This approach continued to allow use of the ACO's quality score in determining the shared loss rate under Track 2 (§ 425.606) and the ENHANCED track (§ 425.610). ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track continued to be subject to a fixed shared loss rate of 30 percent regardless of quality performance. As noted previously, participation in Track 2 and the Track 1+ Model concluded at the end of performance year 2021.

percentile. The outcome measures in the APP measure set are listed in Table 52.

• For performance year 2024 and subsequent performance years: Achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

We noted in the CY 2022 PFS final rule that we had received several comments suggesting that we revert to the previous sliding scale methodology used prior to the alignment with the APP for determining if an ACO has met the quality performance standard (86 FR 65268 and 65269). We stated in the CY 2022 PFS final rule in response to these comments that we would consider proposing to reinstate the sliding scale methodology for determining shared savings and shared losses in the CY 2023 PFS proposed rule for ACOs that report on the three eCQMs/MIPS CQMs. We stated that under such a proposed sliding scale methodology, we would multiply the ACO's MIPS Quality performance category score, based on the ACO's performance on the three eCQMs/MIPS CQMs as reported by the ACO, the two claims-based measures calculated by CMS, and the CAHPS for MIPS survey, by the sharing rate for the ACO's track (or payment model within a track) to determine the ACO's shared savings (86 FR 65269).

(2) Proposals to Scale Shared Savings Based on Quality Performance

In light of the comments received during the public comment period for the CY 2022 PFS proposed rule, we are now proposing to reinstate a modified sliding scale approach for determining shared savings for all ACOs regardless of how they report quality data. In particular, commenters shared their concern that ACOs are now shifting from being compared against other ACOs to broadening this comparison to include all MIPS eligible clinicians (86 FR 65260). We also continue to hear this same concern from a number of interested parties. In addition, if this proposal were limited to eCQM/MIPS CQM reporting, it would require additional complexity specific to the requirements for scaled shared savings and scaled shared losses of the ENHANCED track. Please also refer to section III.G.4.b.(5) of this proposed rule for additional rationale on our proposal to apply the sliding scale approach to all ACOs regardless of how they report quality data.

We propose in § 425.512(a)(4)(ii) and (a)(5)(ii) that, beginning with performance year 2023 and for subsequent performance years, if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate but the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set then the ACO would share in savings (if otherwise eligible) at a lower rate that reflects the ACO's quality performance score. Specifically, the ACO's final sharing rate would be a scaled rate that is calculated by multiplying the maximum sharing rate for the ACO's track (or payment model within a track) by the ACO's quality performance score. The ACO's quality performance score used in this calculation would reflect the ACO's MIPS Quality performance category score plus any health equity adjustment bonus points the ACO is eligible to receive (referred to as the health equity adjusted quality performance score) based on our proposal described in section III.G.4.b.(7) of this proposed rule, if finalized.

For an example of this proposed sliding scale approach for determining shared savings, consider a hypothetical ACO in Level B of the BASIC track in performance year 2023 that met the MSR to qualify for shared savings and achieved a health equity adjusted quality performance score of 45 which is less than the 30th percentile MIPS Quality performance category score based on the unweighted distribution. However, the ACO achieved a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on one of the four outcome measures in the APP measure set. In this example, the ACO would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. We would calculate the scaled final sharing rate for this ACO by multiplying the maximum sharing rate for an ACO in Level B of the BASIC track of 40 percent by the ACO's health equity adjusted quality performance score of 45 (expressed as a percentage) (that is, 40 percent × 45 percent) to obtain a final sharing rate of 18 percent. We would then multiply the final sharing rate by the ACO's total savings (measured on a first dollar basis) to calculate the ACO's shared savings amount before considering the performance payment limit.

We believe the proposed sliding scale approach meets the statutory requirements of section 1899(b)(3)(C) of the Act, which requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. Under our proposal, ACOs would still transition to a higher quality performance standard equivalent to or higher than the 40th percentile to share in savings at the maximum savings rate for their track beginning with performance year 2024. Still, this proposal to reinstate a sliding scale approach for determining shared savings for ACOs would allow for flexibility in order to avoid the all-or-nothing approach as the Shared Savings Program transitions to required reporting of eCQMs/MIPS CQMs beginning with performance year 2025 after the sunsetting of the CMS Web Interface measure set. As recently as performance year 2021, only 12 ACOs reported eCQMs/MIPS CQMs, indicating that most ACOs are still developing their strategy and workflows to combine data across their EHR systems in advance of the requirement to report eCQM/MIPS CQMs beginning in performance year 2025. We believe that the sunsetting of the CMS Web Interface collection, the requirement to report eCQMs/MIPS CQMs beginning in performance year 2025, and the increase in the quality performance standard to share in savings at the maximum savings rate starting in performance year 2024 will increase the stringency of the quality performance requirements under the Shared Savings Program as contemplated under section 1899(b)(3)(C) of the Act.

We believe a scaled approach to the quality performance standard, and thus to the determination of shared savings, would be beneficial because small differences in the distribution of ACOs' MIPS Quality performance category scores and other MIPS reporters' scores for a performance year may result in a large difference in the number of ACOs that fail to meet the quality performance standard as currently defined. Moving away from an all-or-nothing approach to a sliding scale approach to determine shared savings based on ACO quality performance would help to minimize the impact of these fluctuations by allowing ACOs that are close to, but do not achieve the health equity adjusted quality performance score required to share in savings at the maximum sharing rate under their track, to receive some shared savings.

In summary, to implement this proposal, we are proposing to revise the provisions governing the quality performance standard at § 425.512(a)(4)

and (5) to reflect the proposed alternative quality performance standard. Specifically, we propose to revise § 425.512(a)(4) and (5) to provide for a quality performance standard that an ACO must meet in order to share in savings at the maximum sharing rate under its track (or payment model within a track) and an alternative quality performance standard that an ACO would be required to meet in order to share in savings on a sliding scale. We also are proposing to make conforming changes to the methodologies for calculating shared savings under the BASIC track and the ENHANCED track, as specified in § 425.605 and § 425.610, respectively to reflect the proposed sliding scale approach.

We reiterate our statement in the CY 2022 PFS final rule that for performance years 2022, 2023 and 2024 if an ACO: (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs; and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65261). We are proposing that, for performance years 2023 and 2024, an ACO that does not meet these requirements would also not meet the proposed alternative quality performance standard. For performance years 2025 and subsequent performance years, we finalized that if an ACO does not report any of the 3 eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65262). We are also proposing that, for performance years 2025 and subsequent performance years, an ACO that does not meet these requirements would also not meet the proposed alternative quality performance standard. These proposals are reflected in our proposed revisions to § 425.512(a)(4) and (5).

(3) Proposal To Modify Methodology for Determining Scaled Shared Losses for the ENHANCED Track Based on Quality Performance

We are also proposing a modification to the methodology used to determine shared losses for ACOs in the ENHANCED track. Under our current regulations at § 425.610(f)(2), for performance years beginning on or after January 1, 2021, an ACO in the ENHANCED track must meet the quality performance standard in order to have its shared losses scaled based on its quality performance and avoid automatically facing the maximum shared loss rate of 75 percent. We are proposing that for performance year 2023, and subsequent performance years, we would determine the ACO's shared loss rate using a sliding scale approach for an ACO that has losses that exceed its minimum loss rate and either meets the existing quality performance standard applicable for the performance year (that is, an ACO that would currently be eligible for shared losses scaled based on quality performance) or that does not meet that standard but achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set. Under this proposal, an ACO that meets the existing quality performance standard or that meets the new alternative standard would be subject to a scaled shared loss rate equal to 1 minus the product of the maximum sharing rate for the ENHANCED track (75 percent) and the ACO's quality performance score. The ACO's quality performance score used in this calculation would reflect the ACO's MIPS Quality performance category score plus any health equity adjustment bonus points the ACO is eligible to receive (referred to as the health equity adjusted quality performance score) based on our proposal described in section III.G.4.b.(7) of this proposed rule. The scaled shared loss rate would be subject to a minimum of 40 percent and a maximum of 75 percent. An ACO that fails to achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would continue to automatically share in losses at the maximum shared loss rate of 75 percent. Likewise, an ACO that fails to achieve the proposed alternative quality performance standard because it (1) does not report any of the ten CMS Web Interface Measures (for performance year 2023 or 2024) or any of the three eCQMs/MIPS CQMs (for performance year 2025 or subsequent performance year) and (2) does not administer a CAHPS for MIPS survey under the APP as described in section III.G.4.b.(2) of this proposed rule would also automatically share in losses at the maximum rate.

This proposal would, by itself, not materially change the current methodology for determining shared losses for ENHANCED track ACOs that meet the existing quality performance standard (or would meet the criteria for the eCQM/MIPS CQM incentive), but would newly allow for the application of a scaled shared loss rate for ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set, as opposed to these ACOs automatically receiving the maximum shared loss rate under the ENHANCED track of 75 percent as required under the current regulations at § 425.610(f)(2)(ii). That is, more ACOs would have the opportunity to lower their shared loss rate below the maximum rate based on their quality performance.

In practice, an ACO would need to achieve a health equity adjusted quality performance score of higher than 33 and one-third in order to have a shared loss rate below 75 percent under the proposed approach. That is, a score greater than 33⅓ is needed for the scaled shared loss rate formula to yield a value less than 75 percent. For an ACO with a score of exactly 33 and one-third, the shared loss rate calculated by the formula would equal 75 percent. For an ACO with a score below 33 and one-third, the calculated rate would be greater than 75 percent, triggering the application of the maximum shared loss rate of 75 percent.

We note that our proposal to determine the shared loss rate using the ACO's health equity adjusted quality performance score uses language that is different from the phrasing used in the current regulation at § 425.610(f)(2), which describes the shared loss rate as being calculated using ''the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.'' As indicated in the CY 2021 PFS final rule, this approach allowed CMS to continue to scale shared losses by the ACO's quality score under the Shared Savings Program's two-sided models with the highest levels of risk and potential reward, the ENHANCED track and the Track 2 (although performance year 2021 was last year in which ACOs participated under this financial model) (85 FR 84736 through 84740). The phrasing ''the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available'' represents a mechanical description of how the score is calculated to clarify that the scaling factor represented a value between 0 and 1 which, in turn, would ensure that the shared loss rate falls between 0 and 100 percent (before the application of the minimum or maximum shared loss rate). However, upon further consideration, we believe that this phrasing may cause unnecessary

confusion. For example, it does not clarify whether or how applicable MIPS bonus points or quality improvement points would be incorporated or how the calculation would be impacted if the ACO is subject to the extreme and uncontrollable circumstances policy described in § 425.512(b). Furthermore, it does not address the treatment of health equity adjustment bonus points, if the proposed health equity adjustment described in section III.G.4.b.(7) of this proposed rule is finalized. As we have described in prior rulemaking (85 FR 84735), the ACO's MIPS Quality performance category score accounts for any MIPS bonus points and quality improvement points and the extreme and uncontrollable circumstances policy in § 425.512(b), which we are proposing to re-designate as § 425.512(c), indicates how an ACO's quality performance score will be determined if the ACO is affected by an extreme and uncontrollable circumstance. Furthermore, an ACO's health equity adjusted quality performance score would always take on a value between 0 and 100 as the MIPS Quality performance category score itself will always fall between 0 and 100 and the application of the proposed health equity adjustment, if finalized, would be restricted from raising the health equity adjusted quality performance score above 100. As a result, an ACO's health equity adjusted quality performance score could be expressed as a percentage that would also ensure that the scaled shared loss rate falls between 0 and 100 percent (before the application of the minimum or maximum shared loss rate). Therefore, we favor using the phrasing ''health equity adjusted quality performance score'' in describing our proposed methodology for determining the shared loss rate for ENHANCED track ACOs for performance year 2023 onward, and we also note that this phrasing would align with the terminology used in the description of the proposed sliding scale approach for determining shared savings.

For an example of the sliding scale approach for determining shared losses, consider a hypothetical ACO participating in the ENHANCED track in PY 2023 that had total losses above its minimum loss rate and achieved a health equity adjusted quality performance score of 45, which is less than the 30th percentile MIPS Quality performance category score based on the unweighted distribution. If the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set, it would share in losses at a rate that is scaled by the ACO's quality performance score. We would calculate the scaled shared loss rate for this ACO as 1 minus the maximum shared loss rate for the ENHANCED track of 75 percent multiplied by the ACO's health equity adjusted quality performance score of 45 (expressed as a percentage) [1 − (45 percent × 75 percent)] to obtain a shared loss rate of 66.25 percent. We would then multiply this shared loss rate by the ACO's total losses (measured on a first dollar basis) to calculate the ACO's shared losses before consideration of the loss recoupment limit.

We propose to revise the regulatory text in § 425.610(f) to provide for this scaled approach to the determination of shared losses.

(4) Additional Considerations Related to Proposed Modifications to Advanced APM Criteria

Section 414.1415(b)(1) through (3) require that to be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to Advanced APM participants. Specifically, § 414.1415(b)(1) through (3) require, in relevant part, that two quality measures, one of which is an outcome measure, be a factor when determining payment to Advanced APM participants. In the Shared Savings Program, the ENHANCED track and Level E of the BASIC track are currently Advanced APMs, and we expect them to be Advanced APMs in the future. As part of our proposal to permit ACOs that fail to meet the existing criteria under the quality performance standard to share in savings at a lower rate (if otherwise eligible), we are proposing that an ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set. This proposed approach would not meet the current requirements for an Advanced APM at § 414.1415(b)(2) and (b)(3). This is because the proposal permits the use of a single outcome measure as a factor when determining payment. We note that in section IV.A.4.a of this proposed rule, there is a proposal to modify the Advanced APM criteria to allow for a single quality measure to be used to meet both quality measure criteria at § 414.1415(b)(2) and (b)(3). We are aligning our proposal with the proposed modifications to § 414.1415(b)(2) and (b)(3). As such, we are proposing in § 425.512(a)(4)(ii) and (a)(5)(ii) to require that an ACO meet only one of the four outcome measures for the ACO to be eligible to share in savings at a lower rate.

Should the proposal under section IV.A.4.a of this proposed rule not be finalized, we would consider finalizing the following alternate policy based on comments received. Beginning with performance year 2023 and for subsequent performance years, if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate, but the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining measures in the APP measure set, then the ACO would share in savings (if otherwise eligible) at a lower rate that reflects the ACO's health equity adjusted quality performance score. The ACO would consequently be required to meet the performance benchmark on either 2 outcome measures (one outcome measure at the 10th percentile and another measure at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th percentile to maintain consistency with the requirements of § 414.1415(b)(1) through (3).

With respect to shared losses for ACOs in the ENHANCED track, we would consider finalizing a parallel approach that would allow for application of a scaled shared loss rate for ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining measures in the APP measure set.

(5) Broad Applicability of the Proposal To Apply the Sliding Scale Approach To Determining Shared Savings for ACOs

We are proposing to apply the sliding scale approach to determine shared savings for all qualifying ACOs and to determine shared losses for ENHANCED track ACOs regardless of how they report quality data to CMS in order to maintain consistency in the treatment of quality performance across all ACOs.

We believe inclusion of all qualifying ACOs in this proposal regardless of reporting method would be responsive to the concerns expressed by interested parties regarding the perceived inequality in comparing MIPS quality scores between the Shared Savings Program and the traditional MIPS program. Specifically, ACOs have indicated they are limited to reporting the measures included under the APP, whereas traditional MIPS participants have a broader range of measures to select and report (86 FR 65268). Our proposal to implement the sliding scale methodology would allow ACOs that otherwise would not have received any shared savings, but perform well on quality to share in a portion of the savings they achieve, but at a lower rate. This policy would also potentially allow ACOs to make a greater investment in the infrastructure necessary for transitioning to eCQM/MIPS CQM reporting in performance year 2025 or earlier by enabling certain ACOs to receive shared savings that they otherwise would not have received under the current quality performance standard policies. Furthermore, if we were to finalize this proposal, these ACOs would have additional funds available that they could choose to invest in advancing health equity.

We seek comments on all aspects of the proposals to scale shared savings and shared losses discussed in sections III.G.4.b.(2) through (5) of this proposed rule, including the alternative approach if the proposed changes to § 414.1415(b)(2) and (b)(3) are not finalized.

(6) Extension of eCQM/MIPS CQM Incentive

We are separately proposing to revise § 425.512(a)(4) and (5) to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQM/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025. We originally adopted this incentive in the CY 2022 PFS final rule to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in PYs 2022 and 2023 (86 FR 65269). Under the current incentive:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and:
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- A quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

In the CY 2022 PFS final rule, we finalized our proposal to freeze the quality performance standard at the 30th percentile across all MIPS Quality performance category scores for performance year 2023 (86 FR 65269). Therefore, under the current regulations, beginning with performance year 2024 and subsequent performance years, an ACO must achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring (86 FR 65270). To align with the finalized policy from the CY 2022 PFS final rule, we are proposing to update the eCQM/MIPS CQM incentive for performance year 2024 to include this requirement. Under this proposed update to the incentive for performance year 2024:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- A quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

We seek comment on this proposal.

- In addition, we are seeking comment on whether CMS should incorporate the proposed amendments to § 414.1415(b)(2) and (b)(3) described in section IV.A.4.a into the eCQM/MIPS CQM incentive. Incorporating that proposal would result in an ACO only having to achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures to qualify for the incentive in performance year 2023 and performance year 2024.

If we were to modify the eCQM/MIPS CQM incentive to align with the proposed modifications to § 414.1415(b)(2) and (b)(3), we would make corresponding changes to the proposed regulatory text at § 425.512(a)(5)(i)(A)(2) by removing the requirement that an ACO achieve a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set in order to meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable. In addition, we would make corresponding changes to the regulatory text governing the eCQM/MIPS CQM incentive for PY 2023 at § 425.512(a)(4)(i)(B). We note that the requirements to qualify for the eCQM/MIPS CQM incentive for PY 2022 would not be affected by the proposed modifications to § 414.1415(b)(2) and (b)(3).

(7) Health Equity Adjustment for ACOs That Report All-Payer eCQMs/MIPS CQMs, and Are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries

(a) Background and Overview

Health care outcome inequalities exist among patients throughout the United States, and empirical research has found that certain patient characteristics are associated with worse health outcomes. Patients experiencing worse health outcomes often face barriers to accessing health care services and have access to fewer health care providers. This research also provides evidence of the relationships between socioeconomic status/social risk factors and health care outcomes. Section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–183) called for the Secretary of Health and Human Services (HHS) to conduct a study evaluating the effect of individuals' socioeconomic status (SES) on quality measures and measures of resource use under the Medicare program. The Office of the Assistant Secretary for Planning and Education's (ASPE) March 2020 Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing (VBP) Program, provides insight into whether and how value-based programs should account for

beneficiaries' social risk factors such as income, housing, transportation, and nutrition that might adversely affect their access to health care services or health outcomes. A key finding is that dual enrollment status is a strong predictor of poorer health care quality measure outcomes in Medicare's VBP programs, even when accounting for other social and functional risk factors.[206] In addition, several peer-reviewed research studies demonstrate that neighborhood-level factors for those residing in disadvantaged neighborhoods also have a relationship to worse health outcomes for these residents. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[207] [208] [209] [210] [211]

Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels. We believe dual Medicare and Medicaid eligibility and ADI score are good indicators of beneficiaries with high needs. Dual eligibility, an indicator at the beneficiary level, is intended to capture socioeconomic challenges that could affect a beneficiary's ability to access care, while ADI, a neighborhood-level indicator, is intended to capture local socioeconomic factors correlated with medical disparities and underservice. We refer readers to the CY 2022 PFS final rule (86 FR 65382 through 65384) for a detailed review of the literature on health care outcome inequalities. The information included in these articles and reports informed our decision to propose a health equity adjustment in connection with ACO quality performance and our consideration of the appropriate criteria for determining ACO eligibility for the adjustment.

As discussed in section III.G.4.f. of this proposed rule, health equity, addressing health disparities, and closing the performance gap on the quality of care provided to underserved populations continue to be high priorities for the Agency through inclusion of health equity initiatives in CMS programs, and better addressing the social needs of people with Medicare is an important part of this strategy. We are committed to achieving health equity for Medicare beneficiaries by supporting ACOs in quality improvement activities to reduce health disparities, enabling Medicare beneficiaries to make more informed decisions, and promoting provider accountability for health care disparities.[212] [213] Further, CMS has set forth a goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030, and is focused on expanding the reach of ACOs into rural and other underserved communities. Among other considerations for reaching this goal, CMS is examining the use of incentives to close gaps in outcomes for Medicare beneficiaries.[214] In section III.G.2.a. of this proposed rule, we are proposing to provide advance shared savings in the form of AIPs to certain ACOs participating in the Shared Savings Program using beneficiary dual eligibility status and ADI data to determine the amount of quarterly payments. To align with these goals, we are proposing a health equity adjustment that would upwardly adjust quality performance scores for ACOs that serve a high proportion of underserved individuals and achieve high quality performance.

As discussed in section III.G.4.a. of this proposed rule, section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs, while section 1899(b)(3)(A) of the Act provides that that the Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO. We are concerned that our current quality performance standard and the quality performance measures we have adopted do not adequately assess the quality of care provided by ACOs with clinicians who serve a high proportion of underserved individuals. We are similarly concerned that the current quality performance standard and quality measures set do not adequately incentivize all ACOs to provide high quality care to underserved beneficiaries nor do we want to create an incentive for ACOs to avoid underserved populations as we transition to all payer eCQMs/MIPS CQMs because patients with social risk factors tend to have worse quality scores overall. The concern about lower quality scores for underserved populations is magnified in eCQMs compared to reporting via the CMS Web Interface, because all-payer reporting in eCQMs includes quality scores for people with Medicaid (correlating with low-levels of income and increased prevalence social risk factors when compared to people with Medicare); whereas, historical reporting via the CMS Web Interface has only included those quality scores for people with Medicare. Therefore, ACOs that serve a higher proportion of Medicaid enrollees may receive lower quality scores during the switch to eCQMs without an adjustment. In turn, without an adjustment during the switch to eCQMs, ACOs that serve a higher proportion of people with Medicaid or other underserved populations outside of Medicare could be incentivized to avoid underserved populations, delay switching to eCQMs for as long as possible, or even cease participation in the Shared Savings Program altogether. This concern has been raised by interested parties serving large proportions of underserved populations.

We have previously been urged to adopt risk-adjusted quality measures that account for beneficiary

[206] U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP–2nd-Report-Executive-Summary.pdf.*

[207] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' *Annals of Internal Medicine.* No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4251560/.*

[208] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' *Annals of Internal Medicine.* No. 171, pp 91–98, doi:10.7326/M16–2671 (2019), available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6736732/.*

[209] Cheng E, et al., ''Neighborhood and individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' *JAMA Network Open Oncology.* No. 4(12), pp 1–17. doi: 10.1001/jamanetworkopen.2021.39593 (2021), available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8683967/.*

[210] Hutchinson RN, et al., ''Rural disparities in end-of-life care for patients with heart failure: Are they due to geography or socioeconomic disparity?'' *The Journal of Rural Health*, No. 38, pp 457–463, doi: 10.1111/jrh.12597 (2022), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[211] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' *The Journal of Arthroplasty.* No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

[212] CMS website, ''What is the CMS National Quality Strategy?'' *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy* (last accessed June 10, 2022).

[213] CMS Fact Sheet, ''CMS National Quality Strategy,'' April 2022, available at *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet-april-2022.pdf.*

[214] Jacobs D, Rawal P, Fowler L, Seshamani M, ''Perspective: Expanding Accountable Care's Reach among Medicare Beneficiaries.'' New England Journal of Medicine (April 27, 2022), *https://www.nejm.org/doi/full/10.1056/NEJMp2202991.*

characteristics such as geographic location, socioeconomic status, education, race, ethnicity, gender, preferred language, disability status, or health literacy (76 FR 67873). A number of our measures do adjust for certain beneficiary characteristics, such as age and gender; however, we do not broadly adjust measure performance on the numerous demographic characteristics listed. Quality performance approaches based on risk adjustment that are intended to promote equity can mask real differences in quality and make it more difficult to identify and address disparities where they exist. Risk adjustment for social risk factors may also have the unintended effect of setting lower quality standards for underserved populations, rather than ensuring high quality standards for all populations receiving care that is established in the move to eCQMs/MIPS CQM all payer quality measures.

In considering how to modify the existing quality performance requirements under the Shared Savings Program to more fully assess the quality of care furnished by ACOs that serve a high proportion of underserved individuals, we believe that rather than risk adjusting for disparities in the health status of underserved populations, it would be more appropriate to adopt an approach that rewards high quality performance across all populations served by an ACO. For this reason, we are now proposing to revise how we assess the quality of care furnished by ACOs through the creation of a health equity adjustment designed to support those ACOs serving a high proportion of underserved individuals while also mitigating disparities in health care by encouraging all ACOs to treat underserved populations. We believe the proposed approach would also continue encouraging high ACO quality performance, reinforce ACOs' transition to reporting all-payer eCQMs/MIPS CQMs, and provide an incentive for ACOs to provide high quality care to all of the populations they serve. Additionally, because every year a greater proportion of ACOs are making the switch to eCQMs, instituting a health equity adjustment for those ACOs making the switch to eCQMs will allow us to study the impacts and make refinements during subsequent rulemaking.

As described within this section of this proposed rule, we propose that the health equity adjustment would be available for performance year 2023 and for subsequent performance years to an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey. We propose such ACOs may receive up to a maximum of 10 additional points added to their MIPS Quality performance category score. The level of the adjustment would be determined based on the joint consideration of an ACO's performance on quality measures and the population served by the ACO, such that ACOs that perform well on quality measures and serve a higher proportion of beneficiaries who are from underserved neighborhoods (residing in census block group with an ADI national percentile rank of 85 or higher) or are dually eligible for Medicare and Medicaid would receive a higher number of bonus points.

(b) Application of the Adjustment

We propose to apply the health equity adjustment in the form of bonus points added to the ACO's MIPS Quality performance category score. Under this proposed approach, the ACO's health equity adjusted quality performance score would be the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points, if applicable. This proposal would not change the current policy for determining and calculating an ACO's MIPS Quality performance category score.

Under the existing regulations at § 425.512 and under the proposed modifications to the quality performance standard described elsewhere within this proposed rule, there are specific programmatic uses of the ACO's MIPS Quality performance category score. In applying the proposed health equity adjustment to the ACO's MIPS Quality performance category score, which constitutes the ACOs' aggregate, or overall score, across the APP measure set, we propose to limit the application of the health equity adjustment to certain specified Shared Savings Program determinations and calculations. The use of the ACO's health equity adjusted quality performance score in these calculations would allow ACOs that report the eCQMs/MIPS CQMs and provide high quality care to underserved beneficiaries to share in savings at relatively higher sharing rates, or in the case of ENHANCED track ACOs that owe shared losses, to reduce the shared loss rate used to calculate the amount of shared losses owed to CMS. We believe this approach would serve as a means to incentivize ACOs by offering a financial reward for providing high quality care to underserved beneficiaries, further financially support ACOs that serve underserved beneficiaries, encourage ACOs to add ACO participants in underserved areas, and avoid creating adverse incentives for ACOs to avoid underserved populations or the health care providers serving those populations.

We propose to apply an ACO's health equity adjusted quality performance score in determining whether the ACO met the quality performance standard set at the 30th percentile for performance year 2023 as specified under § 425.512(a)(4)(i)(A), or the 40th percentile for performance year 2024 and subsequent performance years, as specified in the proposed revised regulations at § 425.512(a)(5)(i)(A)(*1*) and § 425.512(a)(5)(i)(B), respectively. Use of the ACO's health equity adjusted quality performance score in making this determination would potentially allow more ACOs that provide high quality care to underserved beneficiaries to meet the quality performance standard. Under the Shared Savings Program's current policies, ACOs that meet this quality performance standard share in any savings generated at the maximum sharing rate under their track (or payment model within a track), up to the performance payment limit. For ENHANCED track ACOs that meet the quality performance standard, the ACO's shared losses are scaled based on its quality performance.

We further propose to apply an ACO's health equity adjusted quality performance score in the determining shared savings and losses as specified in certain existing provisions of the Shared Savings Program regulations and under proposed modifications to the regulations as described elsewhere within this proposed rule.

We propose to use an ACO's health equity adjusted quality performance score to determine the final sharing rate for calculating shared savings payments under the BASIC track (under § 425.605(d)) and the ENHANCED track (under § 425.610(d)) for an ACO that meets the proposed alternative quality performance standard allowing for application of a sliding scale based on quality performance, as specified in proposed modifications to § 425.512(a)(4)(ii) and (a)(5)(ii). Among ACOs whose shared savings would be determined according to the sliding scale approach (described in sections III.G.4.b.(2) and (3) of this proposed rule), the application of the proposed health equity adjustment would allow for relatively higher quality performance scores in calculating the final sharing rate and make it possible for an ACO to share in savings at a relatively higher

final sharing rate under its track (or payment model within a track).

For ENHANCED track ACOs that owe shared losses, we propose to apply the health equity adjustment to the ACO's quality performance score used in calculating the ACO's shared loss rate, to allow the ACO to share in losses at a relatively lower rate, based on its quality performance. Specifically, we propose to use an ENHANCED track ACO's health equity adjusted quality performance score in calculating shared losses under § 425.610(f) when the ACO meets the quality performance standard specified under § 425.512(a)(4)(i) or (a)(5)(i) (which includes the incentive for reporting eCQMs/MIPS CQMs for PY 2023 and the proposed extension of the incentive for PY 2024) or meets the proposed alternative quality performance standard under § 425.512(a)(4)(ii) and (a)(5)(ii) allowing for the application of a sliding scale based on quality performance. For an ENHANCED track ACO in the first performance year of its first agreement period that meets the quality performance standard by reporting data via the APP and meeting the data completeness and case minimum requirements in accordance with § 425.512(a)(2), the ACO's quality performance score is utilized in calculating any shared losses under § 425.610(f). Therefore, we also propose to use the ACO's health equity adjusted quality performance score to determine the shared loss rate for such ACOs.

Further, we propose to apply the health equity adjustment in calculating the ACO's quality performance score for an ACO affected by extreme and uncontrollable circumstances if the ACO is able to report quality data via the APP and meet data completeness and case minimum requirements, as provided in § 425.512(b)(3) in the current regulations. As discussed in section III.G.4.b.(8) of this proposed rule, the proposed approach of using an ACO's health equity adjusted quality performance score to determine the ''higher of'' score under the extreme and uncontrollable circumstances policy would have no practical impact on the sharing rate for an ACO that is eligible to share in savings. For an ACO participating in the ENHANCED track that is liable for shared losses, the proposed application of the health equity adjustment could increase the ACO's quality performance score used to determine the ACO's shared loss rate, and thus potentially reduce the amount of shared losses owed to CMS.

(c) Identifying Top Quality Performance Among ACOs reporting eCQMs/MIPS CQMs; Determining the Measure Performance Scaler

We propose the health equity adjustment would be available to an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set and meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey.

We believe that limiting the proposed health equity adjustment to ACOs reporting all-payer measures (eCQMs/ MIPS CQMs) would further encourage ACOs to report all-payer measures in performance year 2023 (while the Web Interface is still an available reporting option). ACOs may opt to report eCQMs/MIPS CQMs in order to have the benefit of the application of the health equity adjustment. As stated previously, the concern about lower quality scores for underserved populations is magnified in eCQMs compared to reporting via the CMS Web Interface, because all-payer reporting in eCQMs includes quality scores for people with Medicaid (correlating with low-levels of income and increased prevalence social risk factors when compared to people with Medicare). ThereforeIn addition, offering a health equity adjustment to ACOs who report all three eCQMs/MIPS CQMs would support ACOs that are serving greater proportions of underserved populations as the shift to all-payer reporting takes place. ACOs not yet familiar with their performance on these measures or how they may be impacted by the change to all-payer populations may be incentivized by this proposal to begin reporting these measures before the full transition occurs.

This proposal takes into account interested parties' concerns regarding challenges in improving quality of care for underserved populations, while recognizing ACOs that provide high quality of care for this population. It also helps address the concerns that we have heard from ACOs that serve higher proportions of people with Medicaid and other underserved populations with regards to all-payer quality reporting during the switch to eCQMs/ MIPS CQMs. As we have noted previously in this section of the proposed rule, social risk factors may adversely affect access to health care services or preferred health outcomes, and dual-enrollment status is a strong predictor of poorer health care quality measure outcomes in Medicare's VBP programs. We acknowledge that using the all payer quality measures as well as outcome measures may make it even more difficult for ACOs that serve underserved populations to achieve the quality performance standard, since all-payer reporting will newly include people with Medicaid as part of quality reporting, and people with Medicaid tend to have a higher amount of social risk factors and lower quality scores. As we discussed in section III.G.4.b(2) of this proposed rule, most ACOs are still developing strategies and workflows to combine data across EHR systems in advance of requirements to report eCQMs/MIPS CQMs. Adding health equity adjustment bonus points to the ACO's MIPS Quality performance category score could allow more ACOs that care for underserved populations to potentially meet the quality performance standard set at the 30th percentile (for performance year 2023) or 40th percentile (for performance year 2024 and subsequent performance years) across all MIPS Quality performance category scores, and therefore support these ACOs reporting eCQMs / MIPS CQMs.

We propose to consider the ACO's performance on all measures in the APP measure set in calculating the health equity adjustment. Refer to Table 53 for the proposed APP measure set for eCQM/MIPS CQM reporting for performance year 2023. To determine an ACO's performance on quality for the purpose of calculating health equity adjustment bonus points, we propose to create three groups based on measure performance (or ''performance groups''): (1) a group comprised of the top third performing ACOs; (2) a group comprised of the middle third performing ACOs; and (3) a group comprised of the bottom third performing ACOs. These groups would be created for each of the six measures independently such that an ACO in the top group based on performance on one measure may be in the bottom group based on performance on another measure. Consistent with current implementation of eCQMs and MIPS CQMs, the three groups would be created by reporting mechanism so that ACOs that report eCQMs would have each measure grouped into a top, middle, and bottom third based on the performance of other ACOs that also report eCQMs. The same methodology would be used for ACOs that report the MIPS CQMs. For the CAHPS for MIPS survey and claims-based measures, ACOs would be compared to all ACOs with data on those measures (including those that reported via the Web Interface, eCQMs, or MIPS CQMs).

We propose to assign to an ACO a value of four for each measure for which its performance places it in the top

performance group, a value of two for each measure for which its performance places it in the middle performance group, and a value of zero for each measure for which its performance places it in the bottom performance group. We would sum the values assigned to each measure in the APP measure set to determine an ACO's total assigned value, which we refer to as the ACO's ''measure performance scaler.'' Under this approach, an ACO could have a measure performance scaler of up to 24 if it is among the top performance group for each measure and thereby received a value of four for each of six measures.

We would assign a value of zero to a measure in certain cases when we would not evaluate the ACO's performance on a measure. For purposes of calculating the health equity adjustment, an ACO would receive zero for a claims-based measure or an eCQM/MIPS CQM for which the ACO does not meet the case minimum requirements at § 414.1380. Similarly, an ACO would receive zero for the CAHPS for MIPS survey in the event it does not meet the minimum sample size requirements. An ACO that cannot meet case minimum requirements or does not have a sufficient sample size to administer the CAHPS for MIPS survey would still qualify to receive the health equity adjustment bonus for those measures that were accurately and completely reported and provided the ACO met the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs.

We also considered and analyzed scaling quality performance for the bottom, middle, and top third of measure performance by different values to evaluate how these values interact with the underserved multiplier (described in detail below) to calculate ACOs' health equity adjustment bonus points. Specifically, we also analyzed assigning a value of 0, 1, and 2 for the bottom, middle, and top third of measure performance, respectively, and decided on proposing 0, 2, and 4 instead. The proposed scaling would allow ACOs that have high levels of an underserved multiplier and high quality performance on most or all measures to receive near or at the maximum of 10 health equity adjustment bonus points. That is, an ACO with an underserved multiplier of 0.45 (or 45 percent) that achieved a measure performance scalar of 24 would receive the maximum of 10 health equity adjustment bonus points. With the alternate scaling approach, this ACO would achieve a measure performance scalar of 12 (that is, a value of 2 for each measure in the top third × 6 measures) but would not receive the maximum of 10 health equity adjustment bonus points even though the ACO would have achieved high-quality while caring for a large proportion of underserved beneficiaries (that is, measure performance scalar of 12 × an underserved multiplier of 0.45 = 5.4 points). Thus, the proposed scaling is consistent with CMS' goal to incentivize greater inclusion of underserved populations and the delivery of high quality care.

(d) Identifying ACOs Serving High Proportions of Underserved Beneficiaries; Determining the Underserved Multiplier

Through the proposed health equity adjustment we seek to improve health equity outcomes by providing incentives to ACOs and their ACO participants and ACO providers/suppliers to achieve high levels of performance on all-payer and outcome focused Medicare quality measures for underserved populations, given the concerns we have heard regarding reporting eCQMs/ MIPS CQMs, which require reporting of data on all patients and are considered all-payer measures. We propose to award higher positive adjustments to ACOs providing higher quality of care to underserved populations, with the amount of the adjustment increasing as an ACO's proportion of underserved beneficiaries increases. Such an approach would support ACOs currently serving a high proportion of underserved individuals while also encouraging all ACOs to treat underserved populations.

We propose to identify ACOs serving larger proportions of underserved beneficiaries, by considering the proportion of dually eligible Medicare and Medicaid beneficiaries and the proportion of beneficiaries residing in areas of high socioeconomic disadvantage within the ACO's performance year assigned beneficiary population. We propose to calculate an ''underserved multiplier'' for each ACO that would be determined using the higher value of either the proportion of an ACO's assigned beneficiary population that is considered underserved based on beneficiaries who are from underserved neighborhoods, identified using ADI data, or the proportion of an ACO's assigned beneficiary population that are dually eligible for Medicare and Medicaid. As noted above, dual eligibility status and ADI are good indicators of socioeconomical disadvantages, with ADI associated with medical disparities and underservice and dual eligibility associated with beneficiary's inability to access care. We would then multiply this underserved multiplier by the aforementioned measure performance scaler to determine the ACO's health equity adjustment bonus points.

We refer readers to the discussion in section III.G.2.a. of this proposed rule for a general description of the ADI data, including the 17 input variables from census data that make up the ADI composite measure. Each census block group's ADI score is ranked nationally, with higher national percentile ranks corresponding to more socioeconomically disadvantaged areas. Census block group's have been found to have stronger associations with hospitalization rates than larger areas used to create ADIs.[215] For each ACO, we would create an underserved multiplier that ranges from zero to one and is based on the higher value of either the proportion of the ACO's performance year assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85 or the proportion of the ACO's performance year assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries).[216] An ADI national percentile rank of at least 85 or above is being used as a cutoff because this is the value at which some empiric studies have demonstrated worse outcomes. In particular, one study demonstrated that 30-day rehospitalization rates did not vary significantly across the least disadvantaged 85 percent of neighborhoods, but hospitalizations within the most disadvantaged 15 percent persons increased with worsening ADI, with a pattern that was similar amongst individuals with congestive heart failure, acute myocardial infarction, and pneumonia.[217] Under the proposed approach, an ACO serving mostly beneficiaries residing in areas of high socioeconomic disadvantage or serving

[215] Maroko AR, et al., ''Integrating Social Determinants of Health With Treatment and Prevention: A New Tool to Assess Local Area Deprivation. Preventing Chronic Disease,'' No. 13(E128), pp.1–5, doi: 10.5888/pcd13.160221 (September 2016), available at *https://www.cdc.gov/pcd/issues/2016/16__0221.htm.*

[216] In computing this proportion, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

[217] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4251560/.*

a larger proportion of dually eligible Medicare and Medicaid beneficiaries would receive a multiplier value closer to one and a larger health equity adjustment to its quality performance score, all else equal. An ACO serving mostly beneficiaries from areas that are not considered to be of low socioeconomic disadvantages and serving a smaller proportion of dually eligible Medicare and Medicaid beneficiaries would not likely receive an underserved multiplier value that meets the proposed floor of 20 percent (described in section III.G.4.b.(7)(e) of this proposed rule), and therefore, would not receive health equity adjustment bonus points. Thus, the result of the underserved multiplier would be that ACOs serving a higher proportion of underserved beneficiaries would be eligible for a greater number of bonus points, assuming they achieve high quality performance. Therefore, the use of the underserved multiplier, combined with the proposed floor to receive any bonus points, is consistent with our goal of rewarding ACOs that include a higher proportion of underserved beneficiaries while delivering high quality care.

The proposed use of ADI and Medicare and Medicaid dually eligible status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries. As described elsewhere in this proposed rule, we are proposing to use ADI and dual eligibility status to determine levels of quarterly AIPs for eligible Shared Savings Program ACOs (see section III.G.2.a. of this proposed rule). These two factors reflect different types of characteristics, which may relate to patient populations differently. An ADI is a multidimensional evaluation of the socioeconomic characteristics of the neighborhoods the beneficiaries live in, and incorporates domains such as education, income, employment, housing, and household characteristics. It also reflects neighborhood factors that may influence health, health care, and care delivery regardless of individual circumstance. Dual Medicare and Medicaid eligibility status is a direct measure of the beneficiary, reflecting their individual income status, and has been shown to be a predicator of worse health outcomes. While there is some overlap between ADI and dual eligibility, we propose to utilize both because they can be used to identify complementary populations that may not be fully recognized using only one of the factors, by taking the higher of the ACO's proportion of assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the ACO's proportion assigned beneficiaries that are dually eligible for Medicare and Medicaid, to determine an ACO's underserved multiplier for calculating health equity adjustment bonus points. Our proposal for the underserved multiplier used for calculating the health equity adjustment and our proposal for calculating quarterly AIPs are directionally aligned in that they both seek to provide greater benefit to ACOs that are serving underserved populations. For the health equity adjustment, we believe use of ACO-level indicators (that is, the proportion of the ACO's performance year assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the proportion that are dually eligible for Medicare and Medicaid) to measure the extent to which an ACO serves underserved populations is preferred to an approach that would establish an underserved multiplier at the beneficiary-level. We believe it would be appropriate to apply an ACO-level underserved multiplier to the measure performance scaler, which would be determined based on ACO-level performance on the measures in the APP measure set. This would allow for alignment between the underserved multiplier and the measure performance scaler to which it is being applied.

Our proposal to use a ''higher of'' either the proportion of an ACO's assigned population residing in census blocks with high ADI or the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid to calculate the underserved multiplier is intended to avoid double-counting overlapping beneficiaries (as could happen when taking the sum of the two proportions), while also allowing an ACO alternate ways to achieve a higher multiplier value, recognizing that no single value would fully represent its population.

We also note that this approach to determining the underserved multiplier based on the ACO's assigned population is a means of approximating the extent to which the ACO and its ACO participants and ACO providers/suppliers are serving underserved beneficiaries. The ADI component of the underserved multiplier would be based on the neighborhood level characteristics among ACO assigned beneficiaries, and these characteristics may generally reflect the social determinants of health in the communities served by the ACO and thus serve as a proxy for the all payer population characteristics and their neighborhoods. The use of dual Medicare and Medicaid eligibility is based on the status of beneficiaries within the ACO.

Although we are proposing to determine the underserved multiplier as the higher of two characteristics—the proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage or the proportion of dually eligible Medicare and Medicaid assigned beneficiaries—we considered an alternative approach that would use a combination of these characteristics in calculating the underserved multiplier. Together these characteristics may be complementary in identifying an ACO's underserved populations, one based on neighborhood characteristics and the other based on dual eligibility status among the ACO's assigned beneficiaries. However, while the two characteristics allow for recognition of the ACO's underserved population at the neighborhood and beneficiary levels, there is potential overlap and thus double-counting with the approach to combine (sum) these characteristics. We seek comment on this alternative approach to calculating the underserved multiplier as the sum of an ACO's proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage and an ACO's proportion of dually eligible Medicare and Medicaid assigned beneficiaries. We note that such an approach would result in a potentially higher underserved multiplier for ACOs, and thereby higher total health equity adjustment bonus points compared to the proposed approach. As a result, under this alternative calculation of the underserved multiplier, more ACOs would likely achieve the maximum of 10 bonus points.

More generally, we note that CMS is considering similar methodologies for determining underserved populations outside of the Shared Savings Program. For example, as discussed in the Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,[218] we are developing a health equity index as a potential methodological enhancement to the Part C and Part D Star Ratings that would summarize performance among groups with social risk factors across multiple measures into a single score. The goal of this health equity index would be to

[218] Available at *https://www.cms.gov/files/document/2023-announcement.pdf*. See for example the discussion of Health Equity Index (Part C and D) on pages 101–103.

advance equity and support underserved communities by incentivizing contracts to perform well serving enrollees with social risk factors such as low-income subsidy (LIS)/dual eligibility and disability.

We also considered alternative approaches for calculating the underserved multiplier that would additionally consider whether an ACO's assigned beneficiaries receive the low-income subsidy (LIS) available under the Medicare Part D prescription drug program. LIS, as an indicator, may capture a different group of low-income beneficiaries than dual eligible status and the eligibility criteria for LIS does not vary by State. Specifically, we considered alternatives under which we would use the LIS indicator in place of, or in addition to, a beneficiary's dual Medicare and Medicaid enrollment status. We also considered using the higher of three factors based on the ACO's performance year assigned beneficiary population: (1) The proportion of the ACO's assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85; (2) the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid; or (3) the proportion of the ACO's assigned beneficiaries receiving LIS. We seek comment on these alternative approaches, or other approaches, to incorporating assigned beneficiaries' LIS status into the underserved multiplier.

(e) Determining the Health Equity Adjustment Bonus Points an ACO Is Eligible To Receive Based on the ACO's Measure Performance Scaler and Underserved Multiplier

We propose the ACO's health equity adjustment bonus points would be calculated by multiplying the measure performance scaler and the ACO's underserved multiplier. However, we are also proposing to impose a number of limitations on the availability of and the amount of the health equity adjustment bonus points.

We propose that ACOs would be ineligible to receive any bonus points if their underserved multiplier is less than 20 percent, thereby establishing a ''floor''on the size of the ACO's underserved population under the health equity adjustment. Imposing a floor of 20 percent for the underserved multiplier, for an ACO to be eligible to receive bonus points, reinforces that the health equity adjustment is intended to reward ACOs that are serving higher proportions of underserved beneficiaries while also achieving high levels of quality performance. We believe this approach is necessary to remain consistent with the goal to reward and incentivize care for these populations. Absent such a floor, ACOs that perform well on quality measures but serve relatively small populations of underserved beneficiaries would be further rewarded, which could create incentives that are inconsistent with the purpose of the health equity adjustment. We anticipate the percent of ACOs meeting the 20 percent floor for the underserved multiplier would increase over time, as existing ACOs seek to expand their reach into underserved communities, and as a result of the proposed new participation options discussed elsewhere in this proposed rule that are designed to foster greater entry into the Shared Savings Program by ACOs that serve underserved communities. For example, among ACOs receiving the proposed AIPs, the amount of the quarterly payments would increase as beneficiaries' risk factors-based scores increase (set to 100 if the beneficiary is dually eligible for Medicare and Medicaid, or set to the ADI national percentile rank of the beneficiary's census block group if the beneficiary is not dually eligible). ACOs receiving AIPs that expand the size of their underserved populations would thereby receive higher amounts of quarterly AIPs to build their care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other proposed criteria for use of the funds (as described in section III.G.2.a. of this proposed rule). Under the proposed health equity adjustment, these ACOs would have a further incentive to deliver high quality of care and thereby perform well on the APP measure set for eCQM / MIPS CQM reporting.

We propose the number of health equity adjustment bonus points to be awarded would not exceed a maximum of 10 points. We believe that limiting the health equity adjustment bonus to a maximum of 10 points strikes a balance between creating an incentive for ACOs to report eCQM/MIPS CQM measures and rewarding ACOs that are high performing on quality and serve higher proportions of underserved beneficiaries, while not overly inflating an ACO's quality performance score. Further, allocating a maximum of 10 points for this bonus would align with the scoring of the required measures under the APP. Previous bonuses within the MIPS program have not exceeded 10 points or been higher than 10 percent of the score the bonus aligns with.[219] [220]

We further propose that the bonus points would be added to the ACO's MIPS Quality performance category score, with the sum capped at 100 percent. This proposed cap at 100 percent would ensure that the application of the health equity adjustment does not cause the ACO's quality performance score to exceed the maximum possible quality performance score an ACO could achieve absent the adjustment. Thus, the proposed cap would align with the current practice which sets the maximum quality performance score at 100 percent.

The health equity adjustment bonus points would be added to the ACO's MIPS Quality performance category score for the purpose of determining whether the ACO meets the quality performance standard for a given performance year by meeting or exceeding the applicable MIPS Quality performance category score percentile and, if applicable, in determining the ACO's final sharing rate or shared loss rate. We note that this proposal to adopt a health equity adjustment would not impact the calculation of the quality performance standard itself. That is, the required percentile (30th for PY 2023 and 40th for subsequent performance years) would continue to be determined across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, and would not reflect any health equity bonus points earned by Shared Savings Program ACOs.

Further, as described in section III.G.4.b.(2) of this proposed rule, under the proposed sliding scale approach for determining shared savings, we would calculate an ACO's final sharing rate as the product of the maximum sharing rate under the ACO's track (or payment model within a track) and the ACO's quality performance score (inclusive of any applicable health equity adjustment bonus points). Similarly, as described in section III.G.4.b.(3) of this proposed rule, under the proposed modifications to the approach to calculating scaled

[219] Centers for Medicare & Medicaid Services (CMS), ''Merit-based Incentive Payment System (MIPS) Scoring Guide for the 2022 Performance Year,'' Quality Payment Program, Updated May 20, 2021, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1201/2020%20MIPS%20Scoring%20User%20Guide.pdf.*

[220] Centers for Medicare & Medicaid Services (CMS), ''Merit-based Incentive Payment System (MIPS) Traditional MIPS Scoring Guide for the 2021 Performance Year,'' Quality Payment Program, Updated April 25, 2022, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1527/2021%20Traditional%20MIPS%20Scoring%20Guide.pdf.*

shared losses for ENHANCED track ACOs, we would calculate an ACO's shared loss rate as 1 minus the product of 75 percent and the ACO's quality performance score (inclusive of any applicable health equity adjustment bonus points), not to exceed 75 percent and not to be less than 40 percent. The proposed cap of 100 percent on the sum of the ACO's MIPS quality performance category score and health equity adjustment bonus points would allow for clarity and consistency in the calculation of the final sharing rates under the proposed sliding scale approach, and for the calculation of the shared loss rate for ENHANCED track ACOs.

Accordingly, the proposed health equity adjustment would enable more ACOs that serve underserved populations and provide high quality care to share in a portion of the savings that they generate as the addition of the proposed health equity adjustment bonus points should allow more ACOs to meet the quality performance standard by meeting or exceeding the applicable MIPS quality performance category score percentile for a given performance year (that is, 30th percentile for PY 2023, and 40th percentile thereafter). For ACOs that meet the proposed alternative quality performance standard described elsewhere in section III.G.4.b. of this proposed rule, the addition of health equity adjustment bonus points to the ACO's quality performance score could increase the final sharing rate used to calculate the ACO's shared savings payment. Finally, for ACOs participating in the ENHANCED track that owe shared losses, the addition of health equity adjustment bonus points could reduce the shared loss rate used to calculate the amount of shared losses owed to CMS.

The combination of the measure performance scaler, based on an ACO's performance on different quality measures, and the underserved multiplier, based on an ACO's unique assigned beneficiary population, results in a range of possible health equity adjustment bonus points that is designed to give the highest rewards to ACOs caring for a disproportionate share of underserved individuals and delivering high quality care. Through the proposed health equity adjustment, ACOs that perform well on measures in the APP measure set for eCQM/MIPS CQM reporting and serve a large proportion of underserved individuals within their assigned beneficiary population would be more likely to receive the maximum number of 10 bonus points, and in turn could see the largest increases in their quality performance score, which in turn, would have the most significant impact on determining the rate at which the ACO shares in savings, or for ACOs under the ENHANCED track, the rate at which the ACO shares in losses. We refer readers to mathematical examples for the steps in the calculation of the health equity adjustment, described in section III.G.4.b.(7)(f) of this proposed rule.

Based on initial modeling, approximately 30 percent of ACOs participating in performance year 2020 would have had an underserved multiplier above the 20 percent floor necessary to qualify for the proposed health equity adjustment. Therefore, we believe the proposed approach could result in a significant number of ACOs earning health equity adjustment bonus points, which in turn would support these ACOs in caring for underserved populations.

Furthermore, by rewarding ACOs when high quality is achieved, the health equity adjustment could create incentives for ACOs to improve care for those who have been historically underserved. This proposed approach, which is designed to upwardly adjust the ACO's quality performance score, lacks additional financial penalties for ACOs that are not meeting high standards of care, which we believe is important as such a downward adjustment could worsen disparities and further jeopardize the ability of these ACOs to care for the populations they serve. We believe this proposal aligns with the broader CMS health equity goals and serves as an important step forward in advancing health equity by providing an incentive for ACOs to care for underserved populations and to provide high quality care to all of the populations they serve, rather than merely adjusting measure performance for patient risk factors.

(f) Calculation Steps and Examples

In this section, we outline the calculation steps and provide examples of the determination of health equity adjustment bonus points and the application of these bonus points (for eligible ACOs) to an ACO's MIPS Quality performance category score. These example calculations illustrate the variability in the health equity adjustment bonus points resulting from the proposed approach, which accounts for both an ACO's quality performance and the ACO's proportion of underserved beneficiaries among its assigned beneficiary population.

Step 1: Calculate the ACO's measure performance scaler.

In the example calculation of the ACO's measure performance scaler, as shown in Table 47, ACOs with ''high'' measure performance have been assigned a value of four for each of the six measures in the APP measure set for having achieved performance on these measures in the top performance group (top third). ACOs with ''middle'' measure performance have a mix of performance in the top performance group (top third, assigned a value of four per measure) and middle performance group (middle third, assigned a value of two per measure) on the six quality measures. ACOs with ''low'' measure performance have a mix of performance in the middle performance group (middle third, assigned a value of two per measure), and bottom performance group (bottom third, assigned a value of zero per measure) on the six quality measures.

TABLE 47: Example of Proposed Measure Performance Scaler Values Assigned for Each Measure

Measure #	ACO 1 and ACO 2 – High measure performance		ACO 3 and ACO 4 – Middle measure performance		ACO 5 and ACO 6 – Low measure performance	
	Performance group	Value	Performance group	Value	Performance group	Value
321	Top third	4	Top third	4	Middle third	2
479	Top third	4	Middle third	2	Bottom third	0
484	Top third	4	Middle third	2	Bottom third	0
001	Top third	4	Top third	4	Bottom third	0
134	Top third	4	Top third	4	Middle third	2
236	Top third	4	Middle third	2	Middle third	2
	Total assigned value per ACO	24	Total assigned value per ACO	18	Total assigned value per ACO	6

Table notes: Measure numbers and names: 321, CAHPS for MIPS; 479, Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups; 484, Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions; 001, Diabetes: Hemoglobin A1c (HbA1c) Poor Control; 134, Preventive Care and Screening: Screening for Depression and Follow-up Plan; 236, Controlling High Blood Pressure.

Step 2: Calculate the ACO's underserved multiplier.

Under the proposed approach, as illustrated in Table 48, the underserved multiplier (column [C]) would be calculated as the higher of the proportion of the ACO's performance year assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85 (column [A]) or the proportion of the ACO's performance year assigned beneficiaries that are dually eligible for Medicare and Medicaid (column [B]). To be eligible for the health equity adjustment bonus points, an ACO would need to have an underserved multiplier of 20 percent (0.2) or higher.

TABLE 48: Example of Proposed Calculation of the Underserved Multiplier Using Factors Based on ACO's Performance Year (PY) Assigned Beneficiaries

ACO characteristics	Proportion of PY assigned beneficiaries with an ADI national percentile rank of at least 85 [A]	Proportion of PY assigned beneficiaries that are dually eligible for Medicare and Medicaid [B]	Underserved Multiplier [C] (higher of [A] or [B])
ACO 1	0.4	0.6	0.6
ACO 2	0.1	0.2	0.2
ACO 3	0.3	0.3	0.3
ACO 4	0.1	0.1	0.1
ACO 5	0.8	0.6	0.8
ACO 6	0.2	0.1	0.2

Step 3: Calculate the ACO's health equity adjustment bonus points.

As shown in Table 49, to calculate the number of health equity adjustment bonus points awarded to an ACO (column [C]), CMS would multiply an ACO's measure performance scaler (Step 1, column [A]) by the ACO's underserved multiplier (Step 2, column [B]).

TABLE 49: Example of Proposed Calculation of the Health Equity Adjustment Bonus Points

ACO characteristics	Measure performance scaler [A]	Underserved Multiplier [B]	Health equity adjustment bonus points [C] (A x B)†
ACO 1	24	0.6	10.0
ACO 2	24	0.2	4.8
ACO 3	18	0.3	5.4
ACO 4	18	0.1	n/a
ACO 5	6	0.8	4.8
ACO 6	6	0.2	1.2

Table notes:
†The maximum number of health equity adjustment bonus points to be awarded would be 10 points.
n/a = an ACO that does not meet the minimum percentage of underserved individuals in its assigned beneficiary population as determined by the underserved multiplier (that is, 20 percent or 0.2).

Step 4: Add the health equity adjustment bonus points to the ACO's MIPS Quality performance category score to calculate the ACO's health equity adjusted quality performance score.

As shown in Table 50, up to 10 health equity adjustment bonus points (Step 3, column [B]) would be added to the ACO's MIPS Quality performance category score (column [A]), with a maximum health equity adjusted quality performance score (column [C]) of 100 percent (that is, the sum is capped at 100).

TABLE 50: Example of Application of the Proposed Health Equity Adjustment to the ACO's MIPS Quality Performance Category Score

ACO characteristics	MIPS Quality performance category score (%) [A]	Health equity adjustment bonus points [B]	ACO's health equity adjusted quality performance score† [C] (A + B; not to exceed 100)
ACO 1	90.0	10.0	100.0
ACO 2	90.0	4.8	94.8
ACO 3	85.0	5.4	90.4
ACO 4	85.0	n/a	85.0
ACO 5	60.0	4.8	64.8
ACO 6	60.0	1.2	61.2

Table notes: †Refer to section III.G.4.b.(8) of this proposed rule for a discussion of how the proposed health equity adjustment would interact with the extreme and unusual circumstances policy.

(g) Incorporating the Health Equity Adjustment Into Shared Savings Program Quality Performance Reports

In the event an ACO reports both the Web Interface measure set and the eCQM/MIPS CQM measure set, the ACO will be assigned the higher of the two quality performance scores for purposes of the MIPS quality performance category (86 FR 65259). If the addition of health equity adjustment bonus points results in the ACO's eCQM/MIPS CQM quality performance score becoming higher than the ACO's Web Interface score (even though it was initially lower), the Shared Savings Program would use the health equity adjusted eCQM/MIPS CQM quality performance score as the ACO's quality performance score. The health equity adjustment would not impact a MIPS eligible clinician's final scores because the health equity adjusted quality performance score would be limited to the Shared Savings Program, where it would be used at the ACO level to determine an ACO's shared savings or losses. Under MIPS, eligible clinicians in ACOs that report both the CMS Web Interface measures and the three eCQMs/MIPS CQMs would receive the higher of either the CMS Web interface or the three eCQMs/MIPS CQMs based on their ACO's MIPS Quality performance category score.

We plan to show the calculation of the health equity adjustment for all ACOs that report on eCQMs/MIPS CQM measures, even if the adjustment would not affect the determination of shared savings or shared losses for the ACO. These calculations would be provided to ACOs in their reconciliation reports package. For example, under § 425.512(a)(2)(ii), an ACO in the BASIC track that is participating in the first performance year of its first agreement period meets the quality performance standard if it reports quality data via the APP and meets data completeness and case minimum requirements specified for the performance year. An ACO meeting these criteria would qualify for the maximum sharing rate under the level of the BASIC track under which it is participating, regardless of the health equity adjustment. Likewise, if such an ACO was participating in a two-sided model under the BASIC track and was liable for shared losses, the ACO would

be subject to a fixed 30 percent shared loss rate that would also be unaffected by the health equity adjustment. For such an ACO, the calculation and reporting of the health equity adjustment would be for purely informational purposes. This information would provide ACOs with an understanding of the proportion of underserved individuals they care for and give ACOs additional insight into this population and opportunities for improvement as they transition to all payer quality measure reporting and develop associated quality improvement strategies and initiatives.

(h) Proposed Modifications to the Regulations

We propose to amend the regulation at § 425.512, which establishes the ACO quality performance standard for performance years beginning on or after January 1, 2021, to include a new paragraph (b) to govern the calculation of an ACO's health equity adjusted quality performance score for performance year 2023 and subsequent performance years, including the policies governing calculation of health equity adjustment bonus points. We are also proposing to make additional conforming changes to § 425.512 to incorporate references to the health equity adjusted quality performance score, through proposed modifications to § 425.512(a)(4)(i)(A), and within proposed revisions to § 425.512(a)(5)(i)(A)(*1*) and (a)(5)(i)(B).[221]

We propose further technical and conforming changes to § 425.512 to redesignate existing paragraph (b) specifying the alternative approach to calculating the quality performance score for ACOs affected by extreme and uncontrollable circumstances, as a new paragraph (c). We also propose a modification to update a cross-reference within the newly redesignated § 425.512(c) for accuracy and to revise newly redesignated § 425.512(c)(3) to specify that we would use the health equity adjusted quality performance score in determining the quality performance score for ACOs affected by extreme and uncontrollable circumstances that report quality data under the APP and meet data completeness and case minimum requirements for performance year 2023 and subsequent performance years (refer to section III.G.4.b.(8) of this proposed rule).

In addition, as described elsewhere within this proposed rule, we propose to revise § 425.605 and 425.610 to specify use of the ACO's health equity adjusted quality performance score determined in accordance with § 425.512(b) for purposes of calculating an ACO's final sharing rate based on a sliding scale. Similarly, under the proposed modifications to § 425.610, we propose to specify use of the ACO's health equity adjusted quality performance score determined in accordance with § 425.512(b) for purposes of calculating the ACO's shared loss rate based on a sliding scale.

In conclusion, we believe the health equity adjustment proposal would support ACOs transitioning to all-payer quality measure reporting, incentivize ACOs to report eCQMs/MIPS CQMs, provide stronger incentives for quality improvement, and recognize high performing ACOs serving underserved populations. We seek comment on all aspects of the proposed methodology. In particular, we seek comment on the proposal to use a three-tiered approach to determine the values assigned to each measure. We seek comment on the scale of values attributed to these three performance groups, as well as the proposal to limit the overall amount of the health equity adjustment to a maximum of 10 bonus points. We seek comment on the proposed requirement that an ACO's underserved multiplier be at least 20 percent for an ACO to be eligible for health equity adjustment bonus points. Finally, we seek comment on alternative methodologies for calculating the underserved multiplier, including using a combination of the ACO's proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage and proportion of dually eligible Medicare and Medicaid assigned beneficiaries, instead of the higher of these factors. We also seek comment on incorporating into the methodology for calculating the ACO's underserved multiplier whether ACO assigned beneficiaries are eligible for the LIS available under the Medicare Part D prescription drug program, including use of a LIS indicator in place of a beneficiary's dual enrollment status.

Given that the proposed approach, if finalized, would be the initial implementation of a health equity adjustment under the Shared Savings Program, we note our intent to monitor the impact of the adjustment to ensure it achieves the goal of rewarding ACOs for high quality performance while caring for larger proportions of underserved beneficiaries. As necessary, we would consider modifications to the design of the health equity adjustment through future notice and comment rulemaking.

(8) Application of Extreme and Uncontrollable Circumstances Policy

The approach used to calculate the quality score for ACOs affected by extreme and uncontrollable circumstances is described in § 425.512(b)(2) and (3) of the current regulations, which we are proposing to redesignate as § 425.512(c)(2) and (3) (refer to section III.G.4.b.(7)(h) of this proposed rule). In summary, for an ACO that fails to report quality data via the APP or that reports quality data but fails to meet the data completeness or case minimum requirements applicable for the performance year, we will set the ACO's quality performance score to the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores for the relevant performance year, as described in § 425.512(b)(2). For an ACO that reports quality data via the APP and successfully meets data completeness and case minimum requirements, we will use the higher of the ACO's own health equity adjusted quality performance score or the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores as described in § 425.512(b)(3).

By design, any ACO that is deemed to be affected by an extreme and uncontrollable circumstance will receive a score that is at least as high as the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores, thus aligning with the quality performance standard applicable for the performance year as described under § 425.512(a) in the current regulations. An ACO affected by an extreme and uncontrollable circumstance that is eligible for shared savings (by virtue of having savings that meet or exceed its MSR) will thus receive a final sharing rate equal to the maximum sharing rate for the ACO's track (or payment model within a track) in the calculation of its shared savings amount, as described in § 425.605(d) (for ACOs participating in the BASIC track) or § 425.610(d) (for ACOs participating in the ENHANCED track). An ACO affected by an extreme and uncontrollable circumstance participating in the ENHANCED track that is liable for shared losses (by virtue

[221] We note that we are proposing to use the term ''health equity adjusted quality performance score'' uniformly in the regulation provisions enumerated in this section of the proposed rule, even in cases where an ACO's MIPS Quality performance category score is based on their reporting of the Web Interface measure set. For such ACOs, the health equity adjustment is assumed to be zero.

of having losses that meet or exceed its minimum loss rate) will face a shared loss rate that considers the ACO's quality performance as described in § 425.610(f). The remainder of this section describes how we propose the existing extreme and uncontrollable circumstances policy would interact with our proposals related to scaled shared savings and losses, described in sections III.G.4.b.(2) and III.G.4.b.(3) of this proposed rule, respectively, and the proposed health equity adjustment, described in section III.G.4.b.(7) of this proposed rule, if finalized.

An ACO that is determined to have been affected by an extreme and uncontrollable circumstance and is eligible for shared savings would already receive the maximum possible sharing rate for its track (or payment model within a track) under the current extreme and uncontrollable circumstances policy. The sharing rate for such an ACO would not be affected by our proposal to re-institute scaled shared savings as described in section III.G.4.b.(2) of this proposed rule. That is, an ACO affected by an extreme and uncontrollable circumstance that meets the proposed alternative quality performance standard, if finalized, would continue to qualify for the maximum sharing rate for its track (or payment model within a track) rather than receiving a sharing rate scaled based on the ACO's quality performance.

An ACO participating in the ENHANCED track that is affected by an extreme and uncontrollable circumstance and is liable for shared losses already receives a shared loss rate that is scaled by the ACO's quality performance under the current extreme and uncontrollable circumstances policy. If such an ACO meets the proposed alternative quality performance standard, if finalized, it would continue to receive a shared loss rate that is scaled by its quality performance. Thus, our proposal to extend scaled shared losses to ENHANCED track ACOs that meet the alternate quality performance as described in section III.G.4.b.(3) of this proposed rule would not, by itself, have a practical impact on the shared loss rate for an ACOs affected by an extreme and uncontrollable circumstance.

With regard to the proposed health equity adjustment, for an ACO affected by an extreme and uncontrollable circumstance that reports eCQMs/MIPS CQMs via the APP, and successfully meets the data completeness requirement at § 414.1340 and case minimum requirement at § 414.1380, we would apply the health equity adjustment bonus points to the ACO's MIPS Quality performance category score, in accordance with our proposed approach described in section III.G.4.b.(7) of this proposed rule before determining the ''higher of'' score under the extreme and controllable circumstances policy. That is, the ACO would receive the higher of the quality performance score equal to the sum of the ACO's MIPS Quality performance category score and the ACO's health equity adjustment bonus points (that is, the health equity adjusted quality performance score) or a score equivalent to the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) across all MIPS Quality performance category scores. We propose to specify the use of the health equity adjusted quality performance score in determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances within the proposed new provision at § 425.512(b) and in determining the ''higher of'' score under the redesignated provisions at § 425.512(c)(3)(ii) and (iii).

The proposed approach of applying the health equity adjustment before determining the ''higher of'' score under the extreme and uncontrollable circumstances policy would have no practical impact on the sharing rate for an ACO that is eligible to share in savings. By design, such an ACO would meet or exceed the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) MIPS Quality performance category score, and qualify for the maximum sharing rate for its track (or payment model within a track) . However, for an ACO participating in the ENHANCED track that is liable for shared losses, the application of the health equity adjustment could increase the ACO's quality performance score used to determine the ACO's shared loss rate, and thus potentially reduce the amount of shared losses owed to CMS.

For an ACO affected by an extreme and uncontrollable circumstance that fails to report quality data via the APP or that reports but fails to the meet data completeness or case minimum requirements, we would continue to set the ACO's quality performance score to the equivalent of the 30th percentile (for PY 2023) or 40th percentile (for PY 2024 and subsequent performance years) MIPS Quality performance category score. Such an ACO would not meet the proposed requirements for the health equity adjustment with respect to reporting and measure performance.

(9) Summary of the Proposals

The following provides an overview of the quality performance standards that would apply in future performance years under these proposals for purposes of determining the rate at which an ACO may share in savings.

Performance Year 2023

- Performance year 2023, to share in savings at the maximum savings rate under its track (or payment model within a track), an ACO must:

++ Report the 10 CMS Web Interface measures in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP, and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or

++ Report the three eCQMs/MIPS CQMs in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, the ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

An ACO that fails to meet the criteria above may qualify to share in savings on a sliding scale based on its performance on any of the 10 CMS Web Interface measures or three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS' calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.

If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs

and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Performance Year 2024

- Performance year 2024, to share in the savings at the maximum rate under its track (or payment model within a track) an ACO must:

++ Report the 10 CMS Web Interface measures in the APP measure set, administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP, and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or

++ Report the three eCQMs/MIPS CQMs in the APP measure set and administer a CAHPS for MIPS survey, while we would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, the ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

- An ACO that fails to meet the criteria above may share in savings on a sliding scale based on its performance on any of the 10 CMS Web Interface measures or three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS' calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.
- If an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Performance Year 2025 and Subsequent Performance Years

- Performance year 2025 and subsequent performance years, to share in savings at the maximum savings rate under its track (or payment model within a track), an ACO must: report quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.
- An ACO that fails to meet the criteria above may share in savings on a sliding scale based on its performance on any of the three eCQMs/MIPS CQMs, CAHPS for MIPS survey, and CMS's calculation of the two claims-based measures in the APP measure set that are reported by the ACO. The ACO must achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set to share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score.
- If an ACO does not report any of the 3 eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

Similarly, we are proposing to modify the methodology for calculating shared losses under the ENHANCED track to account for the sliding scale approach, which would remove the ''cliff'' from the all-or-nothing approach instituted in the CY 2021 PFS final rule (85 FR 84734 through 84736) whereby an ACO that does not meet the quality performance standard would automatically face the maximum shared loss rate of 75 percent. For performance year 2023 and subsequent performance years, we are proposing that an ACO that has losses that exceed its minimum loss rate and either meets the quality performance standard or does not meet that standard but meets the proposed alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would have a shared loss rate that is 1 minus the product of the maximum sharing rate for the ACO's track (75 percent) and the ACO's health equity adjusted quality performance score. The shared loss rate would be subject to a minimum of 40 percent and a maximum of 75 percent.

Under the proposed health equity adjustment, an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, may receive up to a maximum of 10 points added to its MIPS Quality performance category score. This combined score would be the ACO's health equity adjusted quality performance score and would be used in determining whether the ACO met the quality performance standard and in determining scaled shared savings and shared losses, as applicable, as summarized in this section of the proposed rule. This health equity adjusted quality performance score would also be used when applying the extreme and uncontrollable circumstances policy for ACOs that report quality data via the APP and meet data completeness and case minimum requirements.

In addition, we wish to clarify that any requirements that are based on achieving a specified quality performance score on outcome measures are limited to outcome measures that are scored. For example, please refer to Table 52 in section III.G.4.c.(1) of this proposed rule, which indicates the CMS Web Interface measure Depression Remission at Twelve months is an outcome measure that is not scored.

We reiterate our statement in the CY 2022 PFS final rule that for performance years 2022, 2023 and 2024 if an ACO: (1) does not report any of the 10 CMS Web Interface measures or any of the 3 eCQMs/MIPS CQMs; and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard (86 FR 65261). In addition, we are proposing in this proposed rule that, for performance years 2023 and 2024, an ACO that does not meet these requirements would also fail to meet the alternative quality performance standard. Such an ACO would not be eligible to share in savings and, if in the ENHANCED track, would automatically face the maximum shared loss rate.

Additionally, as finalized in the CY 2022 PFS final rule, beginning with performance year 2025, ACOs will be required to report eCQMs/MIPS CQMS, as the Web Interface reporting option

sunsets after performance year 2024 (86 FR 65261).

We note that if our proposal described in section III.G.5.f. of this proposed rule to allow certain ACOs in the BASIC track that do not meet their MSR to receive reduced shared savings is finalized, ACOs meeting the requirements of that policy would face final sharing rates equal to one half of the final sharing rates determined based on the ACO's quality performance, as described in this section.

In Table 51, we summarize the proposed changes to the regulation at § 425.512(a)(4) and (5) to reflect these proposed changes to the quality reporting requirements for performance years 2023 and subsequent performance years.

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TABLE 51: Proposed APP Reporting Requirements and Quality Performance Standard for Performance Year 2023 and Subsequent Performance Years

	Performance Year 2023	Performance Year 2024	Performance year 2025 and Subsequent Performance Years*
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface **or** the 3 eCQMs/MIPS CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.	Same as performance year 2023	ACOs are required to report on the 3 eCQMs/MIPS CQMs and field the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.
Shared Savings Program ACO Quality Performance Standard	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring; or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement and the case minimum requirement for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet either of the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement and the case minimum requirement for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or An ACO that fails to meet the criterion above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

*The CMS Web Interface reporting option sunsets after performance year 2024 and is no longer available beginning with performance year 2025.

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c. Quality Measures

(1) Proposed APP Measure Set

We refer readers to Table 52, which lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for performance year 2022 and subsequent performance years. These are the same measures finalized in the CY 2022 PFS final rule (86 FR 65264 through 65266); however, we note that the Meaningful Measures 2.0 area for each measure has been updated to be consistent with the latest information available on the Meaningful Measures website and a measure number has been added for the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS measure.[222] We are proposing to change the nomenclature of this measure to align with the MIPS program. There are no other proposed changes to this measure except for the name and the addition of a measure number. The measure title we are proposing to use moving forward is Measure 484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. In addition, we have included the measure type in Table 52, for each measure in the measure set. We are including this information to provide ACOs a list of the outcome measures for purposes of meeting the quality performance incentive for reporting eCQMs/MIPS CQMs. This information is also relevant to our proposal to establish an alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score at the 10th percentile on 1 of the 4 outcome measures in the APP measure set, may be eligible to share in savings on a sliding scale. We note inclusion of this information does not change any of the measures in the measure set.

[222] Centers for Medicare and Medicaid Services, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization,* (2022), available at *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

TABLE 52: Measures included in the Final APM Performance Pathway Measure Set for Performance Year 2022 and Subsequent Performance Years [a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	PRO-PM*
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface**	APM Entity/Third Party Intermediary	Safety	Process
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Process
Quality ID#: 370	Depression Remission at Twelve Months***	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Outcome^

[a] We note that we are proposing to not score the following CMS Web Interface measures: the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID#438) and Depression Remission at Twelve Months (Quality ID #370); as these measures do not have benchmarks and we are therefore proposing for them not to be scored for performance year 2022; they are however required to be reported in order to complete the Web Interface data set.

^ Indicates this is an outcome measure.

* Patient-reported outcome-based performance measure (PRO-PM) is a performance measure that is based on patient-reported outcome measure (PROM) data aggregated for an accountable healthcare entity.

**ACOs will have the option to report via the Web Interface for the 2022, 2023, and 2024 performance years only.

*** This measure is not included as one of the four outcome measures for purposes of the Quality Reporting Standard as this measure is not scored.

Table 53 includes the proposed eCQM/MIPS CQM measure set for the Shared Savings Program and outlines the measure types, especially for ACOs that may elect to report on eCQM/MIPS CQMs for PY2023 in order to qualify for the incentive under § 425.512(a)(4)(i)(B).

TABLE 53: Proposed APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2023

Measure #	Measure Title	Measure Type	SSP Quality Performance Standard	
			MIPS Comparable Measure	Outcome Measure
Quality ID#: 321	CAHPS for MIPS	Patient-Reported Outcome	Yes	No
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes	Yes
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes	Yes
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes	Yes
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	Yes	No
Quality ID#:236	Controlling High Blood Pressure	Intermediate Outcome	Yes	Yes

The outcome measures in the APP measure set are listed in Table 52.

The CMS Web Interface collection type under traditional MIPS and the APP includes 10 measures. One of the 10 measures included in the CMS Web Interface collection type is measure Q110: Preventive Care and Screening: Influenza Immunization (also referred to PREV-7 under the CMS Web Interface collection type). Table Group CC of Appendix 1 of this proposed rule includes a proposal to remove measure Q110: Preventive Care and Screening: Influenza Immunization from traditional MIPS for the Medicare Part B Claims, eCQM, and MIPS CQM collection types starting with the 2023 performance period and a proposal to retain the measure for use in relevant MVPs and as a measure in the CMS Web Interface collection type under the APP for purposes of APM Entity-level reporting applicable to Medicare Shared Savings Program ACOs. Because Shared Savings Program ACOs report under the APP, this measure would still be available as a measure under the CMS Web Interface collection type. Please refer to Table Group CC of Appendix 1 where we discuss this proposal further. We are also proposing to make changes to measure specifications for the CMS Web Interface starting in PY 2023. These changes are being proposed to update these measures and to align these measures with the CQM practice workflows and for consistency with clinical guidelines. These proposed changes are discussed in Group Table E of Appendix 1 of this proposed rule.

(2) Proposed Benchmarking Policies for CMS Web Interface Measures for Performance Years 2022, 2023, and 2024

In the CY 2021 PFS final rule, we finalized a change to the quality reporting requirements for purposes of the Shared Savings Program (85 FR 84720 through 84734). Effective for performance year 2021 and subsequent performance years, Shared Savings Program ACOs are required to report quality data via the APP. Under this new approach, ACOs only need to report one set of quality metrics via the APP to satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. In the CY 2021 PFS final rule (85 FR 84720), we explained that the APP measure set would address the highest priorities for quality measurement and improvement, while also reducing reporting burden, promoting alignment of measures and consolidation of reporting requirements across CMS programs, moving payment toward value, and identifying consumers' key quality performance metrics. We also stated that, under the APP, the quality performance score for an ACO will be calculated using the same benchmarks that are established for quality measures available under MIPS (85 FR 84724). Measure benchmarks established under MIPS are based on performance by collection type (*i.e.,* eCQM or MIPS CQM) using data from all available sources, including MIPS eligible clinicians and APM Entities, to the extent feasible, during the applicable baseline or performance period (§ 414.1380(b)(1)). Under § 414.1380(b)(1)(ii)(A), the benchmarks from the corresponding reporting year of the Shared Savings Program are used to score CMS Web Interface measures for purposes of the MIPS Quality performance category. Accordingly, in the preamble to the CY 2021 PFS we indicated that for performance year 2021, we would continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface measures for performance year 2020, which were based on data reported by ACOs, MIPS eligible clinicians, and groups through the CMS Web Interface, and/or a registry from 2016, 2017 and 2018, which would allow us to be consistent with the approach that had been used for scoring CMS Web Interface measures in the Shared Savings Program under § 425.502(b) (85 FR 84724). Furthermore, consistent with the final policy to require ACOs to report quality data via the APP and to score those measures using the MIPS benchmarks, in the CY 2021 PFS final rule, we revised § 425.502 to apply only to performance years beginning on or before January 1, 2020.

Under the policies adopted in the CY 2021 PFS final rule, performance year

2021 would have been the final year in which ACOs would have the option to report either the 10 CMS Web Interface measures or the 3 eCQMs/MIPs CQMs under the APP, and starting in performance year 2022 all ACOs would be required to report the 3 eCQMs/MIPS CQMs (85 FR 84722 and 84723). However, in response to concerns raised by commenters regarding the timeline for implementing eCQM/MIPS CQM reporting requirements under the APP for Shared Savings Program ACOs, in the CY 2022 PFS final rule, we further extended the CMS Web Interface as a collection type under the Quality Payment Program for performance years 2022, 2023, and 2024 for Shared Savings Program ACOs reporting under the APP (85 FR 65261).

When we finalized the extension of the CMS Web Interface as a collection type for the Shared Savings Program, we failed to consider the policies that would apply for purposes of establishing the performance benchmark and minimum attainment level for the CMS Web Interface measures for performance years 2022, 2023, and 2024. As noted previously, when we adopted the requirement that ACOs report quality for purposes of the Shared Savings Program using the APP, our intent was to use the measure benchmarks established under MIPS to score the measures in the APP measure set. However, under § 414.1380(b)(1)(ii)(A), we use the benchmarks from the corresponding reporting year of the Shared Savings Program to score CMS Web Interface measures for purposes of the MIPS Quality performance category. Thus, because the benchmarking policies under § 425.502(b) that were used to establish quality measure benchmarks in the Shared Savings Program prior to the development and implementation of the APP were sunset with the 2020 performance year, there are no policies currently in place that can be used to establish benchmarks for the CMS Web Interface measures in the APP measure set for purposes of determining quality performance under the Shared Savings Program for performance years 2022, 2023, and 2024. Additionally, the absence of benchmarking policies under the Shared Savings Program also impacts MIPS because MIPS uses the CMS Web Interface measure benchmarks established by the Shared Savings Program (§ 414.1380(b)(1)(ii)(B)).

Under the regulation at § 425.502(b)(4)(i), CMS updated the quality performance benchmarks every 2 years. The last set of CMS Web Interface measure benchmarks were established for performance year 2020 and were also used to score the Web Interface measures for performance year 2021 as explained in the CY 2021 PFS final rule (85 FR 84724). In light of the decision to extend the availability of the CMS Web Interface measures under the APP, we now need to establish benchmarks under the Shared Savings Program for these measures for performance years 2022, 2023, and 2024. We believe that the previously established benchmark policies at § 425.502(b) continue to be appropriate for purposes of establishing the quality measure benchmarks and minimum attainment levels and establishing a point scale for the CMS Web Interface measures under the Shared Savings Program for performance years 2022, 2023, and 2024. In the 2015 PFS final rule (79 FR 67927), we finalized the benchmarking proposal to set benchmarks for two years for stability in quality improvement targets while also maintaining reasonable current practices. We propose to use this approach for performance years 2022, 2023 and 2024, using available data for performance year 2022 and 2023 and establishing benchmarks for performance year 2024 which is the last year of Web Interface reporting. We believe the policies are still appropriate as it would provide stability during the transition to all-payer reporting and sunsetting of the Web Interface reporting option, as well as prevent potential variations that could unintentionally create provider burden. In addition, this would allow CMS to score as many of the Web Interface measures as possible, providing stronger incentives for improving and delivering high quality care. Furthermore, using the same policies to establish the benchmarks for the CMS Web Interface measures for performance years 2022, 2023, 2024, would maintain consistency in the development of CMS Web Interface measure benchmarks. Therefore, we are proposing to amend the regulation at § 425.512, which governs the ACO quality performance standard for performance years beginning on or after January 1, 2021, to include a new paragraph (a)(6), which will provide that for performance years 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b).

We acknowledge that to the extent we are proposing to apply these benchmark policies to determine performance benchmarks for the Web Interface measures for performance year 2022, our proposal is retroactive and would require the use of our authority under § 1871(e)(1)(A), which permits the retroactive application of a substantive change in the regulations when the failure to do so would be ''contrary to the public interest.'' We believe this proposal meets the standard for retroactive rulemaking as absent retroactive application of the proposed benchmarking policies the CMS Web Interface measures could not be scored in performance year 2022 for use under the Shared Savings Program in determining shared savings and losses or under MIPS for purposes of the MIPS payment adjustments. We also note that by establishing policies that will allow us to adopt benchmarks for these measures, we will ensure that we can determine the ACOs' quality performance score. If we did not have the authority to establish benchmarks, we would be unable to score ACO quality performance which is used to calculate shared savings and losses inhibiting our ability to successfully implement the Shared Savings Program and recognize and reward ACOs for better care coordination and quality improvement. At the same time, the lack of benchmarks to score quality measures submitted by ACOs would prevent their MIPS eligible clinicians from receiving any MIPS payment adjustment they may be eligible for and could subject them to negative MIPS payment adjustments if they are determined to have poor performance due to the inability to benchmark performance and score the measures submitted by the ACO. In addition, as mentioned above it is in the public interest to establish benchmarks as it should strengthen the incentive for ACOs to deliver high quality and coordinated care consistent with the goals of the Shared Savings Program. We believe there are advantages in having a greater number of scored measures in the CMS Web Interface, including the ability for Shared Savings Program ACOs to report on a larger number of measures to have a potentially higher score, as well as collecting data on measures that can be used for ACOs' quality improvement. An ACO's performance on each measure is assessed against its benchmark to determine points and the overall Quality performance category score. Additionally, when CMS determines that a benchmark cannot be provided for a Web Interface measure, the measure will not be scored for Shared Savings Program ACOs. However, ACOs would still be required to report on any measure that is not scored in order to

complete the CMS Web Interface dataset.

We also need to make a correction from the CY 2022 PFS final rule (86 FR 65266) in which we inadvertently indicated that a benchmark would not be created for the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226). In the CY 2022 PFS final rule (86 FR 65262), we noted three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Cessation: Screening and Cessation Intervention (Quality ID# 226)) did not have benchmarks for performance year 2022 and would not be scored, however, the measures were required to be reported in order to complete the CMS Web Interface dataset. We refer to Table 52 of this proposed rule for a listing of the measures that would not have benchmarks and therefore would not be scored for performance year 2022.

We have determined that we do not have adequate historical data available for benchmarking for the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134) measure for the 2022 performance year. Therefore, CMS is proposing to use the approach in this section of the proposed rule to amend the regulation at § 425.512 to set flat percentage benchmarks for the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134) measure. Since we stated in the CY 2022 PFS final rule (86 FR 65266) that a benchmark would be created for Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134), we find it suitable to use flat percentage benchmarks to measure performance on the measure.

CMS is proposing to score the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure using flat percentage benchmarks under the approach we proposed to amend the regulation at § 425.512 in this section of the proposed rule. The Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) measure triggered flat percentage benchmarks by the policies described at § 425.502(b)(2)(ii) in the previous benchmarking update for the 2020 and 2021 performance years. Therefore, CMS believes it would be advantageous for the measure to keep its flat percentage benchmarks for the 2022 performance year for continuity and that having another scored measure can be beneficial to an ACO's overall quality performance.

As we are proposing for Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134) to be scored using flat percentage benchmarks for the 2022 performance year, ACOs would be scored on eight out of ten CMS Web Interface measures. We believe ACOs might prefer to be scored under a greater number of measures which may improve their overall score and performance for purposes of Shared Savings Program quality assessment. Lastly, use of flat percentages allows ACOs with high scores to earn maximum or near maximum achievement points while allowing room for improvement and rewarding that improvement in subsequent years. Use of flat percentages also helps to ensure that ACOs with high performance on a measure are not penalized as low performers. For the 2023 performance year, we expect to apply flat percentages for the Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134) as the Medicare data may not be unavailable or may be inadequate.

We seek comment on this proposal.

d. Clarifying the Use of Unweighted MIPS Quality Performance Category Scores for Quality Performance Standard Determinations Under the Shared Savings Program

In the CY 2022 PFS proposed and final rules (86 FR 39274 and 86 FR 65271), we stated that the performance year 2018 MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For performance year 2019, the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7. We also stated that, for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores would be calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for scoring for facility-based scoring. Therefore, we are not able to provide performance rate information prior to or during the performance year. Nevertheless, we stated that we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We stated that we would release this historical information on the Shared Savings Program website as soon as it becomes available.

While conducting analysis on the MIPS Quality performance category score data files after the publication of the CY 2022 PFS final rule, we determined that we erroneously used the weighted distribution of Quality performance category scores, rather than an unweighted distribution of Quality performance category scores, to calculate the 30th and 40th percentile MIPS Quality performance category scores provided in the CY 2022 PFS proposed and final rules for 2018 and 2019. The weighted distribution of Quality performance category scores is used in MIPS for final payment calculations. The unweighted distribution of Quality performance category scores submitted by ACOs, groups, and individuals has historically been used to calculate benchmarks for quality measure performance under MIPS and the Shared Savings Program.

In this proposed rule, we are clarifying that, despite this publication error, we use the submission level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Saving Program. We are also clarifying that we use an ACO's submission, which is considered the unweighted distribution of Quality performance category scores, to calculate its MIPS Quality performance category score for purposes of determining whether the ACO meets the quality performance standard under the Shared Savings Program in performance year 2021 and subsequent performance years. As noted above, this policy aligns with the MIPS and Shared Savings Program benchmarking policies and is consistent with our original intended methodology of using the unweighted distribution based on submission data to calculate the MIPS Quality performance category

scores for ACOs as we did to calculate the impacts of the Shared Savings Program quality performance standard proposals in the CY 2021 PFS proposed rule (85 FR 50380).

Based on the use of the unweighted distribution of the Quality performance category scores, for performance year 2018, the MIPS Quality performance category score at the 30th percentile is equivalent to 59.30 and the MIPS Quality performance category score at the 40th percentile is equivalent to 70.80. For performance year 2019, the MIPS Quality performance category score at 30th percentile is equivalent to 58.00 and the MIPS Quality performance category score at the 40th percentile is equivalent to 70.82. For performance year 2020, the MIPS Quality performance category score at 30th percentile is equivalent to 63.90 and the MIPS Quality performance category score at the 40th percentile is equivalent to 75.59. See Table 54 outlining the historical unweighted MIPS Quality performance category scores.

TABLE 54: Historical Unweighted MIPS Quality Performance Category Scores

PY	30th percentile of the MIPS Quality performance category score	40th percentile of the MIPS Quality performance category score
2018	59.30	70.80
2019	58.00	70.82
2020	63.90	75.59

e. Addressing MIPS Quality Performance Category Score Corrections in the Shared Savings Program's Reopening Authority

As finalized in the CY 2021 PFS final rule, beginning with performance year 2021, the Shared Savings Program will use an ACO's MIPS Quality performance category score under the APP to determine whether the ACO has met the Shared Savings Program's quality performance standard. In turn, the ACO's quality performance informs the amount of shared savings earned or shared losses owed. There are interactions between the Shared Savings Program's financial reconciliation timeline and the Merit-Based Incentive Payment System (MIPS) targeted review process and other MIPS Quality performance category score-related corrections, and as a result, CMS may learn of errors in the calculation of MIPS Quality performance category scores after the issuance of an initial determination of financial performance under the Shared Savings Program.

CMS has sole discretion over when to reopen determinations of ACO shared savings and shared losses to correct errors for good cause. We believe that it would be appropriate to clarify the circumstances in which we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. In this section, we discuss these circumstances and explain how we will approach such reopenings, the process by which we would make any corrections, and the manner in which we will adjust shared savings payments to the ACO or shared loss recoupments from the ACO, if applicable.

Under § 425.315, CMS may reopen the initial determination or a final agency determination under 42 CFR part 425 subpart I and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. Good cause may be established when: (1) there is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or (2) the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

In the June 2016 final rule, we noted in response to comments, that in order to provide an opportunity for CMS to consider updated information and make other adjustments to payment determinations across all ACOs, and to minimize program disruptions for ACOs resulting from multiple reopenings, we would, to the extent feasible, use a unified reopening (as opposed to multiple reopenings) to correct errors for a given performance year (81 FR 38001). In addition, we indicated that we would consider other ways to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments to correct errors for good cause under the reopening provisions. For example, we explained that if, during the 4-year time period following notification of the initial payment determination, we determine that a correction needs to be made to a prior performance year's results for good cause, we would seek to potentially adjust the shared savings payment to the ACO or the shared loss recoupment from the ACO for a *subsequent* performance year (81 FR 38001). To illustrate, we stated that if an ACO that generated shared savings for the second performance year of its agreement period owed CMS money based on a correction made to the payment determination for the prior performance year, we might be able to deduct the amount owed prior to making the shared savings payment for the current year (subject to the general Shared Savings Program requirement for ACOs to repay monies owed to CMS within 90 days of notification of the obligation). We also explained that ACOs would not be able to delay recoupment of any payments owed by notifying us of a possible error that could merit reopening (81 FR 38002). Instead, we stated that if we later determine that a correction should be made, we would subsequently combine, if feasible, the revised calculation of shared savings or shared losses for the affected performance year with the financial reconciliation for the most recent performance year. For example, we indicated that we would add any amount owed to the ACO as a result of a reopening, to any shared savings payment for which the ACO is eligible for the most recent performance year. We indicated that we expected to be able to provide ACOs with sufficient details regarding these corrections that they would be able to attribute the additional payment or recoupment arising from the reopening internally

and, as applicable, distribute additional funds to or collect amounts from the appropriate ACO participants from the prior PY.

Further, we explained that in considering when to reopen an error for good cause, we intend to strike a careful balance between important Medicare program integrity concerns that payments be made timely and accurately under the Shared Savings Program with our desire to minimize unnecessary operational burdens for ACOs and CMS, and to support the ACOs' ability to invest in additional improvements to increase quality and efficiency of care (81 FR 38001). To achieve this careful balance in objectives, for reopenings to address CMS technical errors, we indicated that we may consider whether an error satisfies a materiality threshold, such as when it affects 3 percent of the total amount of net shared savings and shared losses for all ACOs for the applicable performance year. This was a threshold based on guidance from the Government Accountability Office (GAO) for financial audits of Federal entities.[223] We explained that although ACOs are not Federal entities, we believed it would be reasonable to consider the GAO guidance in determining when a technical error has a material effect across all ACOs, such that we should use our discretion to reopen for good cause.

As finalized in the CY 2021 PFS final rule, beginning with PY 2021, Shared Savings Program ACOs are required to report quality data for purposes of the Shared Savings Program via the APP under the Quality Payment Program (85 FR 84720 through 84736). An ACO will meet the Shared Savings Program quality performance standard if the ACO achieves a quality performance score that is equivalent to or higher than the percentile specified for the relevant performance year, across all MIPS Quality performance category scores (§ 425.512(a)(3) and (4)). In the CY 2022 PFS final rule, we finalized an extended phase-in of the quality performance standard under the Shared Savings Program (§ 425.512(a)(3) through (5); 86 FR 65266), which we discuss in detail in section III.G.4.b. of this proposed rule. Because ACOs are now reporting quality data via the APP and receiving MIPS Quality performance category scores, we are concerned that CMS may learn of errors in the calculation of MIPS Quality performance category scores after the Shared Savings Program has issued financial reconciliation reports (which are initial determinations of an ACO's financial performance for the applicable performance year). For this reason, we believe that it is appropriate to clarify the circumstances in which we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

We issue (typically in the summer) MIPS performance feedback reports for the previous performance year to MIPS eligible clinicians, eligible practices that submitted data as a group, virtual groups, and APM entities. For ACOs, the MIPS performance feedback report includes data on ACO quality performance, but does not indicate whether the ACO has met the Shared Savings Program's quality performance standard. Each ACO's MIPS Quality performance category score is calculated using the ACO's performance on the measures reported under the APP (ACO-reported measures, CAHPS for MIPS survey measure, claims-based measures), any applicable MIPS bonus points, and quality improvement points.[224]

MIPS eligible clinicians, groups and APM entities (such as ACOs) may request a targeted review of the calculation of the MIPS payment adjustment factor pursuant to § 414.1385. The MIPS targeted review submission period starts once the MIPS performance feedback report is issued and remains open for 60 days with the reviews concluding on a rolling basis, and may extend into October or November (§ 414.1385(a)(2)). If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores with regard to measures, activities, performance categories (including the quality performance category), and the final score, as well as the MIPS payment adjustment factors (§ 414.1385(a)(6)). For Shared Savings Program ACOs, changes to MIPS Quality performance category scores could affect the quality performance standard and have an impact on the amount of shared savings earned or shared losses owed by the ACOs. Further, because we are proposing to incorporate a sliding scale approach as part of the quality performance standard, a change to an ACO's own MIPS Quality performance category score could also have an impact on the amount of shared savings earned by the ACO or the amount of shared losses owed to CMS under the ENHANCED track.

CMS aims to deliver the Shared Savings Program financial reconciliation reports that incorporate MIPS Quality performance category scores for the previous year to ACOs in August on an embargoed basis (that is, ACOs may not publicly release the information in these reports), and typically 2–3 weeks later an unembargoed basis, at which point ACOs can publicly share the information in the reports. Unlike the MIPS performance feedback reports, these reports indicate whether an ACO has met the Shared Savings Program's quality performance standard. Under the proposed policies in this proposed rule, an ACO's health equity adjusted quality performance score for a performance year and the determination of whether the ACO met the Shared Savings Program quality performance standard would affect the determination of shared savings for that performance year and, for ACOs participating in the ENHANCED track, the amount of any shared losses owed. The unembargoed financial reconciliation reports constitute an initial determination of the ACO's financial performance for the applicable performance year. With the initial determination, we also send demand letters to ACOs that indicate the amount of shared losses that must be paid in full to CMS within 90 days of receipt. CMS initiates payments to ACOs that have earned shared savings for a performance year in September of the year following the applicable performance year in order to pay with the correct fiscal year funds. Given that the timeline for conducting a MIPS targeted review of the MIPS performance feedback report may extend past the date that we issue unembargoed financial reconciliation reports, we may learn of errors in the calculation of MIPS Quality performance category scores after the issuance of initial determinations of financial performance under the Shared Savings Program.

As we discussed previously in this section, we believe that it is appropriate to clarify how we would exercise our discretion to reopen for good cause in the event of errors in the MIPS Quality performance category scores, such as

[223] GAO updated the guidance in 2020 and the recommended materiality threshold remains 3 percent. S*ee Financial Audit Manual,* Volume 1, Updated April 2020, 230–4, available at *https://www.gao.gov/assets/gao-18–601g.pdf.*

[224] *See* 2021 APP Toolkit, *2021 APM Performance Pathway for Shared Savings Program Accountable Care Organizations (ACOs) Guide,* slide 15, available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1495/2021%20APM%20Performance%20Pathway%20(APP)%20Toolkit.zip.*

those identified through the MIPS targeted review process, that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. We are contemplating an approach under which we would reopen initial determinations of ACO financial performance to account for any corrections that have been made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings [225] or the amount of shared savings or shared losses, with no restrictions on the magnitude of the error or the number of ACOs affected. Under this approach, the determination of whether there has been an error in the determination of a MIPS Quality performance category score that affects the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO; whether a correction would be warranted; and the timing of any correction would be within the sole discretion of CMS as provided in § 425.315(a)(4).

For illustrative purposes, we describe how a correction to a MIPS Quality performance category score, based on a targeted review or other changes to the MIPS Quality performance category score, could affect the determination of whether an ACO is eligible for shared savings. In this example, an ACO participating under the BASIC track received an initial determination indicating that it met the MSR requirement and that it met the quality performance standard because it achieved a MIPS Quality performance category score that is equivalent to or higher than the percentile specified as the quality performance standard for that performance year. Because the ACO was otherwise eligible to share in savings for the performance year, CMS issued an initial determination that the ACO was eligible to share in savings at the maximum sharing rate under its track (or payment model within a track). Several weeks after that initial determination is issued, CMS learns of an error in the calculation of the MIPS Quality performance category scores that caused the ACO's health equity adjusted quality performance score to be higher than it would have been absent the error. As a result, the ACO's actual health equity adjusted quality performance score was less than the percentile specified as the quality performance standard for that performance year. In this example, we would exercise our discretion to reopen the determination of the ACO's financial performance for good cause to correct the ACO's MIPS Quality performance category score. As a result of this correction, the ACO would no longer have a health equity adjusted quality performance score that is equivalent to or higher than the percentile specified as the quality performance standard for that performance year. Accordingly, the ACO would no longer meet the quality performance standard and thus would be ineligible for shared savings or alternatively might be eligible to receive a reduced shared savings payment in the event we finalize the proposed sliding scale approach.

Alternatively, a correction to a MIPS Quality performance category score could affect the amount of shared savings or shared losses owed to an ACO. For example, an ACO under the ENHANCED track might receive an initial determination indicating that it owes shared losses to CMS calculated at the maximum shared loss rate because it: (1) Exceeded the minimum loss rate; and (2) it failed to meet the quality performance standard for that performance year.[226] Several months after that initial determination is issued, as a result of a MIPS targeted review, we learn of an error in the calculation of the ACO's MIPS Quality performance category score that caused the ACO's health equity adjusted quality performance score to be lower than it would have been without the error. In this case, we would exercise our discretion to reopen the determination of the ACO's financial performance for good cause to correct the ACO's MIPS Quality performance category score. In making this correction, the ACO now achieves a health equity adjusted quality performance score that causes it to meet the quality performance standard. While the ACO would still owe shared losses because it exceeded the minimum loss rate, the amount of shared losses it owes could be reduced based on the ACO's corrected health equity adjusted quality performance score as we would now determine the ACO's shared loss rate using a sliding scale approach.

In the event that we learn of errors in the calculation of MIPS Quality performance category scores (from a MIPS targeted review or some other MIPS Quality performance category score-related corrections) that change the percentile score an ACO must achieve in order to meet the quality performance standard, we would exercise our discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO due to the miscalculation of MIPS Quality performance category scores. Moreover, as noted previously, if we determine that there is good cause to make a correction to a prior performance year's determination of ACO financial results as a result of corrections made to MIPS Quality performance category scores, we would seek to potentially adjust the shared savings payment to the ACO or any shared loss recoupment from the ACO for a subsequent performance year. This approach would not alter the current requirement that ACOs repay shared losses within 90 days after notification of the initial determination of shared losses.

We believe this approach is flexible and balanced and would allow us to exercise our discretion to reopen initial determinations of ACO financial performance for good cause to account for any corrections that have been made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO. We acknowledge that from year to year, corrections could sometimes advantage individual ACOs and sometimes disadvantage individual ACOs.

We seek comment on this clarification of when we would exercise our discretion to reopen for good cause when either an initial determination or a final agency determination regarding an ACO's financial performance needs to be corrected as a result of any corrections made to MIPS Quality performance category scores that affect the determination of whether an ACO is

[225] Unlike shared savings, the determination of whether an ACO is eligible for shared losses is not dependent upon whether the ACO meets the quality performance standard. If an ACO meets or exceeds the minimum loss rate, it will be responsible for sharing losses. *See, for example,* § 425.610(b)(3).

[226] Section 425.610(f)(2)(ii). Under the current regulations, an ENHANCED track ACO that is liable for losses and fails to meet the quality performance standard automatically faces the maximum shared loss rate of 75 percent, whereas an ACO that meets the quality performance standard would face a shared loss rate that is scaled by the ACO's quality performance (subject to a minimum and maximum rate). We note that in the event we finalize our proposal to extend the sliding scale approach to determining shared losses to ENHANCED track ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set, a larger number of ACOs could potentially have their shared losses reduced as the result of a MIPS targeted review.

eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

f. Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development—Request for Information (RFI)

In the CY 2022 PFS proposed rule, we solicited comments on addressing health disparities and promoting health equity (86 FR 39269 and 39270). We indicated our belief that assessing Shared Savings Program ACOs' quality performance on a broader population can have a positive impact on the quality of care for all groups, including Medicare beneficiaries (86 FR 39270). Additionally, we affirmed our expectation that the transition to all-payer eCQM/MIPS CQMs would help to address disparities and promote health equity by promoting a single standard of care across all patients receiving care from practices participating in Shared Savings Program ACOs regardless of location or racial/ethnic group (86 FR 39270). We sought comment and recommendations on how ACOs could utilize their resources to ensure all patients have access to equal care and how to improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare (86 FR 39270). Furthermore, we sought comment on how we could encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives, including whether any adjustments should be made to quality measure benchmarks to take into account ACOs serving vulnerable populations (86 FR 39270).

We received many comments in support of CMS' commitment to advancing health equity and addressing health disparities within the Shared Savings Program, including several comments supporting stratification of data and quality measures by social risk factors such as race and ethnicity and inclusion of health equity measures in the program. In addition, we received some feedback expressing concerns that eCQM/MIPS CQM measures would divert resources into electronic systems instead of focusing on health equity. Commenters also noted that changes to the payment structure under the Shared Savings Program could help ACOs improve infrastructure to address health equity and disparities. As we stated in the November 2011 final rule (76 FR 67872), our principal goal in selecting quality measures for the Shared Savings Program has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes.

Health equity and addressing health disparities continue to be high priorities for the agency through inclusion of health equity initiatives in CMS programs, and better addressing the social needs of people with Medicare is an important part of this strategy. Communities experiencing persistent poverty or inequality tend to disproportionately experience unmet social needs.[227] According to the U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion's Healthy People 2030, which has a strong focus on eliminating health disparities and creating equitable opportunities for people to live healthy lives, social determinants of health have a major impact on people's health, well-being, and quality of life. This report cites safe housing, transportation, neighborhoods and access to nutritious foods as examples of social determinants of health.[228] For health care providers to help improve health outcomes by addressing these needs for people with Medicare, there is growing evidence to support screening patients for social needs, referring patients who screen positive to local community-based organizations that can help patients address these needs, and finally ensuring that follow-up is obtained and the social needs are addressed. In addition, screening patients for social needs would allow clinicians to develop treatment plans, if needed, which would better capture a patient's unique needs and priorities.[229]

In this proposed rule, we are seeking comment on the potential future inclusion of two new structural measures in the APP measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. The National Quality Forum (NQF) provided conditional support for these two measures during the 2021–2022 cycle and indicated the measures would be appropriate for consideration in the Shared Savings Program.[230] The measure Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. This screening for health-related social needs is consistent with the priorities of the agency and the Shared Savings Program, including Meaningful Measures 2.0 priority areas specific to equity. Meaningful Measures 2.0 includes addressing measurement gaps such as development and implementation of measures that reflect social and economic determinants.[231]

The measure Screening for Social Drivers of Health assesses the rate at which providers screen beneficiaries 18 years and older for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Below are the numerator and denominator for the measure:

- *Numerator:* The number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance, and interpersonal violence.
- *Denominator:* The number of beneficiaries 18 and older in practice (or population).

We refer readers to IV.A.10.c.(1)(c)(i) of this proposed rule and Table Group A of Appendix 1 of this proposed rule, where we discuss the proposed health equity measure for purposes of MIPS, ''Screening for Social Drivers of Health.'' We refer readers to section IV.A.10.c.(1)(d) of this proposed rule for the request for information regarding measure development related to health equity under MIPS.

If the measure is adopted in the traditional MIPS program, we will consider proposing, in future rulemaking, the addition of this measure as an eCQM/MIPS CQM under the APP beginning in PY 2025, once the Web Interface reporting option sunsets and the transition to reporting eCQMs/MIPS CQMs is complete. It is important to note that the measure specifications are not being developed for electronic health record (EHR) reporting at this time, but would be considered for purposes of any future rulemaking.

[227] Centers for Medicare and Medicaid Services CMS Office of Minority Health, *CMS Framework for Health Equity 2022–2032,* (2022), available at website *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity.*

[228] U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion, *Healthy People 2030,* refer to website *https://health.gov/healthypeople/priority-areas/health-equity-healthy-people-2030.*

[229] AHRQ.gov, *Identifying and Addressing Social Needs in Primary Care Settings, (2021),* refer to *https://www.ahrq.gov/sites/default/files/wysiwyg/evidencenow/tools-and-materials/social-needs-tool.pdf.*

[230] National Quality Forum, *MAP Final Reports,* (2022), available at website *https://www.qualityforum.org/setting_priorities/partnership/map_final_reports.aspx.*

[231] Centers for Medicare and Medicaid Services, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization,* (2021),available at website *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

Per the Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care final report,[232] this measure would also address a significant performance gap ''in which 84 percent of physician offices do not screen for all five needs, even though approximately one-third of patients would screen positive for one or more social needs.'' We believe the potential inclusion of this measure in the APP measure set reported by Shared Savings Program ACOs could advance health equity by ensuring ACO participants better understand the needs of the patients that they serve. We expect that, by screening for these social determinants of health, the ACO would accomplish the first step in helping people with Medicare address their social needs—understanding their needs. This screening would also enable clinicians to develop treatment plans, if needed, that are focused on beneficiaries' unique needs and priorities. We may consider including additional quality measures in the future that would assess how well ACOs address the social needs of Medicare beneficiaries more directly. We note that any changes to the measures included in the APP measure set, including the addition of new measures, would be proposed through future rulemaking.

We are also seeking input on Screen Positive Rate for Social Drivers of Health, which assesses the percentage of patients who screened positive for health-related social needs. We are interested in feedback from ACOs and other interested parties on the value of implementing a quality measure that indicates a patient's social needs as a part of the quality of care provided to them.

We are soliciting comments on the potential addition of these two social determinant of health measures to the APP measure set reported under the Shared Savings Program if these measures are adopted for the traditional MIPS program and other ways to incorporate health equity into public reporting. We also seek comment on the following:

- How to best implement the measures and how they could further drive health equity and health outcomes under the Shared Savings Program?
- What are the possible barriers to implementation of the measures in the Shared Savings Program?
- What impact would the implementation of these measures in the Shared Savings Program have on the quality of care provided for underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? While supporting flexibility, how can we advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

Separately, we refer you to section III.G.2. of this proposed rule where we are proposing to implement AIP, which would provide advance shared savings payments based on assigned beneficiary dual eligibility status and ADI score to new, low revenue ACOs that are inexperienced in performance-based risk. Eligible ACOs may use the funds to invest in support strategies to address patient challenges related to social determinants of health, such as developing transportation services, remote access technologies, telemonitoring, language, literacy and cultural competency services, offering meals, and partnering with community-based organizations to address a patient's social needs, further aligning policies under the Shared Savings Program with initiatives to advance health equity and be responsive to social needs. We are committed to prioritizing the advancement of health equity through program policies with a focus on underserved populations, improving data collection and analysis on social needs and health disparities, and incorporating actionable measures addressing health disparities in future notice and comment rulemaking. We note that, should measures that screen for social needs be adopted in the future, data gathered through such screenings may support the prudent use of AIPs by ACOs.

g. Addition of New Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions—Request for Information (RFI)

We are also seeking to gather ACOs and other interested parties input on the potential and modified questions in the CAHPS for MIPS Survey pertaining to health disparities and price transparency, which would support implementation of the No Surprises Act. The No Surprises Act includes provisions specific to improvements in transparency and greater oversight of prescription drug and medical costs.

The CAHPS for MIPS Survey measures 10 key domains of patients' experience of care that are referred to as summary survey measures (SSMs) and include the following:

- Getting Timely Care, Appointments, and Information
- How Well Providers Communicate
- Patient's Rating of Provider
- Access to Specialists
- Health Promotion and Education
- Shared Decision Making
- Courteous and Helpful Office Staff
- Care Coordination
- Stewardship of Patient Resources
- Health Status and Functional Status

CAHPS surveys are an integral part of the Shared Savings Program's efforts to meaningfully assess patient experience and have been a requirement of the program since the November 2011 final rule establishing the Shared Savings Program (76 FR 67872). We stated in that final rule that we believe there is evidence that the CAHPS survey assesses important aspects of provider-patient interaction that can be influenced by an ACO's level of organizational support, training and incentive structure (76 FR 67874). In the CY 2021 PFS final rule (85 FR 84722), we finalized that beginning in PY 2021, Shared Savings Program Accountable Care Organizations (ACOs) are required to report quality data via the APP. As part of the APP, Shared Savings Program ACOs are required to administer the CAHPS for MIPS survey (85 FR 84730 through 84732).

The No Surprises Act,[233] which took effect on January 1, 2022, includes provisions such as billing protections for consumers covered under group and individual health plans as well as certain improvements to transparency and oversight of prescription drug and medical costs (86 FR 36872). The No Surprises Act aligns with President Biden's goals of increased transparency, competition, and fairness across healthcare systems.[234] We are firmly committed to the advancement of the President's vision for health care and the resulting benefits, which include empowerment of consumers in making more informed and value-based health care decisions. We believe certain provisions of the No Surprises Act are

[232] National Quality Forum, MAP 2021–2022 Considerations for Implementing Measures Final Report – Clinicians, Hospitals, and PAC–LTC, (2022), available at website *https://www.qualityforum.org/Publications/2022/03/MAP_2021–2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx.*

[233] Title I of Division BB of the Consolidated Appropriations Act, 2021, Public Law 116–133.

[234] Centers for Medicare and Medicaid Services, *HHS Kicks Off New Year with New Protections from Surprise Medical Bills*, (2022), available at website *https://www.cms.gov/newsroom/press-releases/hhs-kicks-new-year-new-protections-surprise-medical-bills.*

relevant in consideration of the questions we are seeking input on for the CAHPS for MIPS survey. On [date], the Office of Personnel Management, the Internal Revenue Service, the Department of Labor, and CMS issued an interim final rule entitled Requirements Related to Surprise Billing; Part 1 (86 FR 36872). This interim final rule notes that regulations promulgated under the No Surprises Act should ensure that all individuals, particularly those from underserved and minority communities, trust and believe information they receive related to healthcare costs and coverage (86 FR 36875). The agencies also note that regulations issued pursuant to the No Surprises Act should encourage regulated entities to address barriers to access of care, including trust concerns with the health care system, and to communicate with individuals in a language they can understand, in a respectful way that addresses cultural differences, and at an appropriate level of literacy (86 FR 36875).

As previously described in this section of the proposed rule, in developing policies for the Shared Savings Program, we are also committed to prioritizing the advancement of health equity through program initiatives with a focus on underserved populations, improving data collection and analysis on health disparities, and incorporating actionable measures addressing health disparities in future notice and comment rulemaking.

An article in the Journal of the American Medical Association titled *Patient-Reported Experiences of Discrimination in the U.S. Health Care System* describes a cross-sectional national survey conducted in 2019 that included 3,253 U.S. adults. This survey was designed to determine the prevalence, frequency and main types of discrimination experienced in the health care system.[235] Of the 2,137 survey respondents, 458 (21.4 percent) indicated they had experienced discrimination in the health care system, and 330 (72 percent) of those who had experienced discrimination reported experiencing it on more than one occasion. The most frequently reported type of discrimination experienced in the health care system was racial/ethnic discrimination, followed by educational or income level discrimination, weight, sex and age. According to the authors, the survey results suggested that health care discrimination experiences were more prevalent than previously recognized and a need existed for additional analysis of how discrimination related to structural inequities and social determinants of health.

One of the additional questions that we are considering adding to the CAHPS survey would be specific to health disparities and focuses on the patient's experience with discrimination based on the characteristics of the patient. The question we are seeking input on is ''In the last 6 months, did anyone from a clinic, emergency room, or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you?'' The potential responses include; health condition, disability, age, culture, sex (including sexual orientation and gender identity) and income. We seek feedback on additional or modified potential response categories for this health disparities question. Feedback received through this RFI, along with analysis and findings from the testing of the survey question in other programs and future testing in this program would be used to inform future rulemaking.

We also believe that this question aligns with the goals of the quality performance standard under the Shared Savings Program. Section 1899(b)(3)(C) of the Act provides that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs, and the Secretary shall seek to improve the quality of care furnished by ACOs over time, in part, by specifying new measures. Inclusion of this question to the CAHPS for MIPS Survey would allow CMS to better understand the extent to which patients perceive discrimination in their health care, in alignment with HHS efforts to provide culturally and linguistically appropriate services (CLAS). The National CLAS Standards, were developed by the HHS Office of Minority Health and provide a blueprint for individuals and healthcare organizations to implement services that are respectful of health beliefs, practices and needs of diverse patients with the goal to advance health equity, improve quality of services and assist with elimination of disparities.[236] In addition, the Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (Behavioral Health Guide) underscores the ways in which the National CLAS Standards can improve access to behavioral health care, promote quality behavioral health programs and practice, and ultimately reduce persistent disparities in mental health and substance use treatment for underserved minority communities.[237]

In addition, inclusion of a health disparities question in the CAHPS for MIPS survey would align with the five priorities outlined in the CMS Framework for Health Equity 2022–2032.[238] The priorities include both system and community level approaches for achievement of equity in Medicare and include:

- *Priority 1:* Expand the Collection, Reporting and Analysis of Standardized Data;
- *Priority 2:* Assess Causes of Disparities Within CMS Programs and Address Inequities in Policies and Operations to Close Gaps;
- *Priority 3:* Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities;
- *Priority 4:* Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services; and
- *Priority 5:* Increase All Forms of Accessibility to Health Care Services and Coverage.

In addition, we believe that the inclusion of a health disparity question in the CAHPS for MIPS Survey would assist CMS in understanding the patient's perspective of their treatment during health care visits as well as provide insight for health care providers on how to improve upon patient interactions, promotion of health equity and delivery of care. In addition, this question is already being tested in the Medicare Advantage program and based on the findings from this testing in the Medicare Advantage program, we may consider including this question in the CAHPS for MIPS survey through future rulemaking. Including the question in the CAHPS for MIPS survey would provide consistency across CMS programs in learning more about patient

[235] Nong P., Raj M., Creary M., *Patient-Reported Experiences of Discrimination in the U.S. Health Care System, JAMA Network*, (2020), available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774166.*

[236] U.S. Department of Health and Human Services Office of Minority Health, *Cultural and Linguistic Competency, National CLAS Standards,* (2021), available at website *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6.*

[237] U.S. Department of Health and Human Services Office of Minority Health, *Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care,* (2012), available at website *https://www.minorityhealth.hhs.gov/minority-mental-health/clas/.*

[238] Centers for Medicare and Medicaid Services, *CMS Framework for Health Equity 2022–2032,* (2022), available at website *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/equity-plan.*

experiences with discrimination from various health care providers.

We are also seeking input on the addition of questions to the CAHPS for MIPS survey specific to price transparency. These questions would build upon the goals of the No Surprises Act to improve transparency and oversight of drug and medical costs, allowing patients to have more information on which to base their healthcare decisions. We also note that the questions under consideration are patient focused, which is one of the goals of the CAHPS for MIPS survey. Currently, the CAHPS for MIPS survey includes the question ''In the last 6 months, did you and anyone on your health care team talk about how much your prescription medicines cost?'' [239] We are considering adding a question that would be more general in nature and encompass additional areas of a patient's care, such as whether the patient talked with anyone on their health care team about the cost of health care services and equipment. An additional question or questions encompassing a patient's health care costs would allow us to better understand how extensively health care providers are considering and discussing costs with their patients, so they are more able to make informed health care decisions. We believe the inclusion of such questions would also support the goals of the Shared Savings Program which include promotion of accountability for patient populations and fostering coordination of items and services under Medicare Parts A and B. The program also encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery. ACOs work to reduce fragmentation in patient care and cost by giving their ACO participants and ACO providers/suppliers the incentives and tools to deliver high-quality, coordinated, team-based care that proactively promotes improved health for all patients.[240]

We are also considering revisions to the CAHPS for MIPS Survey measure in order to make it more broadly applicable to specialty groups in addition to primary care groups. In particular, we are requesting public comment on shortening the survey to remove survey items that are relevant only to primary care providers. Alternately, we may create an alternate shortened survey version for specialty groups while maintaining the existing survey questions for primary care groups.

In summary, we are seeking information and feedback from commenters on: (1) the potential future inclusion of health disparities and price transparency questions and whether there are other questions that should also be considered for potential future inclusion in the CAHPS for MIPS survey; and (2) whether they have any input on creating a shortened version of the CAHPS for MIPS Survey measure such that it is more applicable to specialty groups. Feedback received through this RFI, along with analysis and findings from the testing of the survey questions in other programs and future testing in this program would be considered to inform future rulemaking, as previously indicated.

5. Financial Methodology

a. Overview

In this section of this proposed rule, we are proposing modifications to the financial methodologies used under the Shared Savings Program. We propose a combination of modifications to the Shared Savings Program's benchmarking methodology and financial models to encourage sustained participation by ACOs in the program and remove barriers for ACOs serving medically complex and low-income populations. Specifically, we are proposing to revise the benchmarking methodology by: incorporating a prospective, external factor for updating the benchmark (section III.G.5.c.(3) of this proposed rule); adjusting rebased benchmarks to account for an ACO's prior savings (section III.G.5.c.(4) of this proposed rule); and reducing the impact of negative regional adjustments on ACO benchmarks (section III.G.5.c.(5) of this proposed rule). We are also seeking comment on alternatives to the combination of policies proposed in sections III.G.5.c.(3) through (5) which would be aimed at addressing concerns about the effect of an ACO's assigned beneficiaries on regional FFS expenditures used in establishing, adjusting, updating, and resetting an ACO's historical benchmark (section III.G.5.c.(6) of this proposed rule). We are also proposing changes to how we calculate regional factors used in benchmarking to reflect differences in prospective and preliminary prospective assignment (section III.G.5.d. of this proposed rule), how we conduct annual risk adjustment to better account for medically complex, high cost populations and to guard against coding initiatives (section III.G.5.e. of this proposed rule), and we are proposing a methodology to increase opportunities for low revenue ACOs participating in the BASIC track to share in savings (section III.G.5.f. of this proposed rule). We discuss ongoing considerations of the impact of the PHE for COVID–19 on ACO expenditures (section III.G.5.g. of this proposed rule), and we are proposing to exclude from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program a proposed new supplemental payment under the IPPS for IHS/Tribal Hospitals and hospitals located in Puerto Rico (section III.G.5.h. of this proposed rule). We conclude with a discussion of the proposed modifications to 42 CFR part 425, subpart G (section III.G.5.i. of this proposed rule), to incorporate the related proposed changes discussed throughout this section, as well as certain technical and conforming changes, and corrections. Our specific proposals are discussed in detail in the following sections.

b. Statutory and Regulatory Background on Establishing and Updating the Benchmark and Determining Savings

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for

[239] Centers for Medicare and Medicaid Services, *2022 CAHPS for MIPS Survey Sample Copy*, (2022), available at QPP Resource Library website *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1894/2022%20CAHPS%20for%20MIPS%20Survey%20Sample%20Copy.pdf.*

[240] Centers for Medicare and Medicaid Services, Affordable Care Act's Shared Savings Program Continues to Improve Quality of Care While Saving Medicare Money During COVID–19 Pandemic, (2021), available at website *https://www.cms.gov/newsroom/press-releases/affordable-care-acts-shared-savings-program-continues-improve-quality-care-while-saving-medicare.*

Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking and savings determination methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking and savings determination methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

The rules governing the benchmarking calculations and determination of shared savings and losses are set forth in the regulations at 42 CFR part 425, subpart G. In the November 2011 final rule establishing the Shared Savings Program, we adopted policies for establishing, updating, and resetting the benchmark at § 425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to § 425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at § 425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in § 425.601. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (*see* November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; and December 2018 final rule, 83 FR 68005 through 68030).

Calculations related to determination of shared savings and shared losses are specified in § 425.605 for ACOs participating under the BASIC track, and § 425.610 for ACOs participating under the ENHANCED track (formerly referred to as Track 3). In the June 2015 final rule, CMS established Track 3, constituting the program's highest level of risk and potential reward (80 FR 32771 through 32781). In the December 2018 final rule, CMS renamed Track 3 the ENHANCED track (see, for example, 83 FR 67841), and established the BASIC track, which includes a glide path with five Levels (A through E) (83 FR 67841 through 67857). The BASIC track's glide path allows eligible ACOs to begin under a one-sided model and incrementally advance to higher levels of risk and reward. We refer the reader to earlier rules for details on the development of the current policies for determining shared savings and losses under the BASIC track and ENHANCED track.

In the May 8, 2020, COVID–19 IFC (85 FR 27578 through 27582), we established adjustments to benchmark and performance year expenditure calculations to address the COVID–19 pandemic as specified under § 425.611. In the CY 2021 PFS final rule (85 FR 84771 through 84785), we summarized and responded to public comments received on these adjustments, and finalized the regulation at § 425.611 with modifications.

Details on the Shared Savings Program's financial methodology are included in Specifications documents. Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, January 2022), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1.* For details on Shared Savings Program policies to address the impact of COVID–19 pandemic and the resulting public health emergency, refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology, Specifications of Policies to Address the Public Health Emergency for COVID–19 (December 2020), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf.*

c. Strengthening Participation by Reducing the Effect of ACO Performance on Historical Benchmarks, Addressing Market Penetration, and Strengthening Incentives for ACOs Serving Medically Complex and High Cost of Care Populations

(1) Regulatory Background

To establish an ACO's historical benchmark for an agreement period, CMS uses ACO historical expenditures for beneficiaries that would have been assigned to the ACO in the 3 most recent years prior to the start of the agreement period. As the statute requires the use of historical expenditures to establish an ACO's benchmark, the per capita costs for each benchmark year must be trended forward to current year dollars and then a weighted average is used to obtain the ACO's historical benchmark. Section 1899(d)(1)(B)(ii) of the Act also requires that the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. Therefore, in the November 2011 final rule establishing the Shared Savings Program, we adopted policies for trending forward expenditures for benchmark year (BY) 1 and BY2 to BY3 dollars (76 FR 67924 and 67925), and for updating the benchmark for each performance year during the ACO's agreement period (76 FR 67925 through 67927).

Over the 10 years since the Shared Savings Program was first established, we have used a variety of approaches for determining the trend and update factors to make an ACO's cost target more independent of its own expenditures, including using factors based on national expenditures, regional expenditures, or both. With these approaches, we have maintained a degree of parity between the factors used to trend and update the benchmark, either based on national FFS expenditures, regional FFS expenditures, or a blend of national and regional FFS expenditures.

In the November 2011 final rule establishing the Shared Savings Program, we adopted policies at § 425.602 establishing trend and update factors based on national FFS expenditures (76 FR 67924 through 67927). We finalized use of a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward BY1 and BY2 to BY3 dollars. We also finalized use of a flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the Original Medicare FFS program to update the benchmark for each performance year of the agreement period. We described our belief that using a trend factor based on a national growth rate in Medicare Parts A and B expenditures and an update factor calculated as a flat dollar amount equivalent of the projected absolute amount of growth in national FFS expenditures provides a relatively higher expenditure benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost high growth areas would therefore have an incentive to reduce their rate of growth to bring their costs more in line with the national average;

while ACOs in low cost low growth areas would have an incentive to maintain or improve their overall lower spending levels (76 FR 67924 through 67927).

In the June 2015 final rule, we adopted policies for resetting the benchmark for ACOs entering a second agreement period in 2016 at § 425.603(b) (80 FR 32786 through 32796). These policies addressed concerns about the use of an ACO's prior performance years as benchmark years in second and subsequent agreement periods [241] by weighting each benchmark year equally and incorporating an adjustment to account for the average per capita amount of savings generated during the ACO's prior agreement period. We refer to this adjustment as a ''prior savings adjustment.'' We believed that incorporating a prior savings adjustment into the benchmarking methodology for renewing ACOs entering a second agreement period in 2016 would encourage ongoing program participation by ACOs that had lowered expenditures during their first agreement period. We noted that absent this adjustment, an ACO that previously achieved success in the program may elect to terminate its participation in the program rather than face a lower benchmark that reflects the lower costs for its patient population during the performance years of its prior agreement period (80 FR 32788 through 32791). When proposing this policy in the December 2014 proposed rule (79 FR 72838 and 72839), we highlighted the advantages of the prior savings adjustment, including increasing incentives for ACOs to remain in the program and continue generating shared savings and improving quality due to the prospect of a higher benchmark in future agreement periods. Furthermore, we hypothesized that adjusting benchmarks for prior performance would increase the likelihood of ACOs entering two-sided risk models. The prior savings adjustment adopted in the June 2015 final rule applied only to ACOs entering a second agreement period beginning in 2016 because we subsequently finalized an alternative methodology incorporating factors based on regional FFS expenditures to establish, adjust and update the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years.

In the June 2016 final rule (81 FR 37953 through 37991), we modified the benchmarking methodology to finalize an approach that incorporated factors based on regional FFS expenditures when resetting (or rebasing) and updating ACO historical benchmarks, as specified in § 425.603(c) through (f). We replaced the national trend factor used in the rebasing methodology with a methodology incorporating regional trend factors. This revised rebasing methodology applied beginning in 2017 to determine rebased historical benchmarks for ACOs renewing for a second or subsequent agreement period under the Shared Saving Program. We also adopted a phased approach to adjusting the rebased benchmark to reflect a percentage of the difference between an ACO's historical expenditures and FFS expenditures in the ACO's regional service area. A higher percentage would be used in calculating this regional adjustment to the ACO's rebased historical benchmark for the ACO's third agreement period (or fourth agreement period for ACOs that entered a second agreement period in 2016) and all subsequent agreement periods. The finalized methodology also included an annual update to the rebased benchmark to account for changes in regional FFS spending, replacing the update based solely on the absolute amount of projected growth in national FFS spending. We finalized an approach to calculate regional FFS expenditures, which included defining an ACO's regional service area to include all counties where one or more beneficiaries assigned to the ACO reside, calculating risk adjusted county FFS expenditures for the ACO's regional service area using the assignable beneficiary population residing in each of the counties included in the ACO's regional service area, and weighting county-level FFS costs by the proportion of the ACO's assigned beneficiaries in the county. The approach adopted in the June 2016 final rule was designed to address concerns about an ACO's influence on its historical benchmark by making the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region by incorporating regional expenditures into the determination of an ACO's historical benchmark and applying a methodology for risk adjustment that accounted for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area. This approach, which was sunset through subsequent rulemaking that was finalized in December 2018, applied to determine the rebased historical benchmark for ACOs that renewed their participation agreement for a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019.

In the December 2018 final rule (83 FR 68005 through 68030), we adopted policies at § 425.601 that expanded the use of regional factors in establishing, adjusting, and resetting historical benchmarks to all ACOs, including ACOs in a first agreement period, for agreement periods beginning on July 1, 2019, or in subsequent years. These policies sought to address concerns about ACOs influencing their own regional trends by using a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark under § 425.601(a)(5) and a blend of national and regional update factors to update the historical benchmark to the performance year under § 425.601(b) (83 FR 68024 through 68030). Under this approach, the weight applied to the national component of the blended trend and update factors increases with an ACO's penetration in its regional service area. We also finalized changes to limit the magnitude of the regional adjustment to address CMS' concerns about windfall gains for low-spending ACOs and to reduce disincentives for ACOs serving medically complex patients (83 FR 68017 through 68024). Specifically, we established a symmetrical cap on the regional adjustment to the historical benchmark equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. We also modified the schedule of weights used to phase in the regional adjustment at § 425.601(f), to reduce the maximum weight from 70 to 50 percent for all ACOs and to slow the phase-in of weights for ACOs with higher spending than their regional service area.

In earlier rulemaking, we have acknowledged that the use of factors based on regional FFS expenditures in calculating benchmarks will have varying effects on ACOs depending on each organization's individual circumstances (*see*, for example, 81 FR 37954 through 37957, and 81 FR 37975 through 37977; also 83 FR 68017 and 68026).

(2) Overview of Considerations for Modification to the Benchmarking Methodology

In the CY 2022 PFS proposed rule (86 FR 39291 through 39295), we summarized select aspects of the Shared Savings Program's benchmarking methodology and related concerns that have been expressed by ACOs and other interested parties and solicited comments. We discussed some of our

[241] 79 FR 72835 and 72836.

considerations based on our initial analyses of these concerns about the methodology for calculating regional FFS expenditures used in certain benchmark calculations, specifically the regional adjustment and the blended national-regional growth rates used in trending and updating the benchmark. We sought comment on possible approaches for removing an ACO's assigned beneficiaries from the assignable beneficiary population used in the regional expenditure calculations to address concerns raised by ACOs and other interested parties that the current approach results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which they suggest may tend to be rural ACOs (86 FR 39292). In the CY 2022 PFS proposed rule (86 FR 39293), we noted the potential, based on initial simulations, for mixed effects on ACOs from modifications to the benchmark methodology to remove the ACO's assigned beneficiaries from the calculation of regional FFS expenditures. We also specified that it would be important to consider the extent to which market penetration should be considered in benchmark calculations, noting that relatively few ACOs have high market shares (86 FR 39293). We also sought comment on alternative benchmarking methodologies that may incorporate data sources other than Medicare FFS expenditure trends, such as by incorporating factors based on Medicare Advantage rates, or other published trends (86 FR 39294). We sought comment on alternate approaches to updating the historical benchmark, noting that in order for us to use our authority under section 1899(i)(3) of the Act to implement payment methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, those payment methodologies must be determined to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures (86 FR 39294).

In the section of the CY 2022 PFS final rule entitled ''Comments on Considerations Related to the Use of Regional FFS Expenditures and the Risk Adjustment Methodology in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark'' (86 FR 65295 through 65306), we summarized comments received, and noted that we would take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies. We noted that we would propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking. In the following discussion we provide select information on the comments received and previously summarized, and we refer readers to the aforementioned section of the CY 2022 PFS final rule for more complete summaries of commenters' suggestions.

Several commenters, including MedPAC, did not support removing ACO assigned beneficiaries from the regional FFS expenditure calculations (86 FR 65298). MedPAC expressed concern this would reward historically low spending ACOs without improving their efficiency of care while at the same time further reducing participation incentives among high spending ACOs that were likely to have the greatest opportunity for efficiency improvements.[242] Many commenters favored removing ACO assigned beneficiaries from the regional reference population (86 FR 65298 through 65302), with some commenters suggesting this approach in combination with other modifications to the benchmarking methodology, such as to expand the definition of regional service area, or to modify the blended national-regional growth factors used in trending and updating the ACO's historical benchmark. Some commenters sought clarity on the approach that would be used to remove an ACO's assigned beneficiaries from the assignable population of beneficiaries used to determine regional FFS expenditures given anticipated mixed effects on ACOs, including the impact on ACOs serving patients with high costs of care (86 FR 65298). Commenters offered differing perspectives on unintended consequences that could result from removing ACO assigned beneficiaries from regional FFS expenditures, with some commenters suggesting that this could also inadvertently increase incentives for patient selection and market consolidation (86 FR 65300 and 65301). Commenters offered a variety of alternative approaches (86 FR 65301 and 65302). For example, MedPAC suggested that ACOs selecting prospective assignment be offered a trend factor that is set prospectively prior to the start of the performance year and developed utilizing local and national estimates as is already done for benchmarking under the Global and Professional Direct Contracting Model (to be redesigned and renamed as the ACO Realizing Equity, Access, and Community Health (REACH) Model beginning January 1, 2023).[243]

We have continued to investigate the commenters' concerns and consider their suggestions, and have performed additional modeling and analysis. We take seriously ACOs' and other interested parties' concerns about the Shared Savings Program's benchmarking methodology. There are three core concerns (or dynamics) which we seek to address in this rule through proposed modifications to the Shared Savings Program's benchmarking methodology:

- How to ensure rebased benchmarks remain accurate and serve as a reasonable baseline, when benchmark years correspond to performance years of the ACO's preceding agreement period, requiring ACOs to continually beat their own performance (also referred to as a ''ratchet effect'').
- How to address a single ACO's or multiple ACOs' collective effects on their own regional expenditures, which are used to calculate the regional adjustment and the regional portion of the trend and update factors.
- How to ensure the benchmarking methodology results in benchmarks of sufficient value to encourage program entry and continued participation by ACOs, ACO participants, and ACO providers/suppliers serving medically complex, high cost populations, and to address selective participation in the program by ACOs, ACO participants, and ACO providers/suppliers resulting from the program's benchmarking methodology.

As indicated in the regulatory background in section III.G.5.c.(1) of this proposed rule, we have taken incremental steps to address these dynamics through previous rulemaking, such as: using factors based on regional FFS expenditures to trend and update the ACO's rebased historical benchmark instead of a prior savings adjustment, followed by modifications to use blended national-regional growth factors in trending and updating the ACO's historical benchmark beginning with the ACO's first agreement period; incorporating a regional adjustment to the benchmark in the rebasing methodology, followed by modifications

[242] Letter from MedPac to Chiquita Brooks-LaSure, Administrator, CMS (September 9, 2021), regarding File code CMS–1751–P, available at *https://www.regulations.gov/comment/CMS-2021-0119-26001.*

[243] We note that the Global and Professional Direct Contracting Model has gained experience using a prospectively set trend factor utilizing local and national estimates as part of benchmarking; this element of the benchmarking methodology will continue when the model transitions to the redesigned ACO REACH Model on January 1, 2023.

to apply the regional adjustment beginning with the ACO's first agreement period, and to adjust the phase-in of weights used in determining the regional adjustment over time; and modifying the risk adjustment methodology to account for changes in severity and case mix of the ACO's assigned beneficiaries during the performance year. While these approaches have made some progress to address the aforementioned dynamics, as discussed elsewhere in this proposed rule, we continue to receive feedback from ACOs and other interested parties that additional modifications to the benchmarking methodology are needed to further reduce impacts from rebasing and the regional effects of increasing market penetration by ACOs, and to support ACOs, and in particular ACOs serving medically complex, high cost populations, as they work to achieve the program's goal of lowering growth in Medicare FFS expenditures.

There is some evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may already deter participation among ACOs with spending above their regional benchmark and those serving medically complex, high cost populations. For example, in performance years 2017 through 2019, just over 80 percent of ACOs subject to a regional adjustment received a positive adjustment, indicating their spending was lower than spending in their regional service area. More recently, the share of ACOs receiving a positive regional adjustment is closer to 90 percent. This pattern suggests selective participation behavior, where ACOs that have already achieved efficiency or that are serving beneficiaries with lower health risks are more likely to participate. Providers with the greatest opportunity to reduce spending (those that are inefficient and high spending relative to their region and that would receive a negative regional adjustment if they formed an ACO) are less likely to participate under the current methodology, limiting savings for the Medicare program. Additional analysis has suggested that ACOs receiving the largest negative regional adjustments tend to be those serving beneficiaries with high average risk scores and/or high proportions of beneficiaries dually eligible for Medicare and Medicaid. This further suggests, that these ACOs may be higher cost relative to their regions as a result of caring for the highest needs populations rather than being inefficient, and that ACOs serving medically complex, high cost populations may have more difficulty participating in the Shared Savings Program.

We believe that addressing the concerning dynamics in the benchmarking methodology, combined with modifications to the risk adjustment methodology and to participation options targeted at improving participation by ACOs serving medically complex, high cost populations,[244] would further CMS' goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[245] This goal has informed our consideration of how to approach potential modifications to the benchmarking methodology, and in particular to consider approaches that would allow for a potentially significant increase in participation in the Shared Savings Program.

We also note that we are continuing to consider additional modifications to the Shared Savings Program benchmarking methodology that may be needed to ensure the program's longer-term sustainability. MedPAC discussed ratchet effects from rebasing and ACOs' affecting their own regional expenditures in its November 2021 public meeting[246] and January 2022 public meeting.[247] Many of the commissioners appear to support a longer-term approach under which CMS would update ACOs' benchmarks annually using ''exogenous'' factors, meaning factors not impacted by the individual or collective performance of ACOs. This approach, which has been referred to as ''administratively set benchmarks'', would use a combination of administratively determined factors and projected growth in volume and intensity of FFS services, to account for whether an ACO is high or low spending relative to its region. However, at least one commissioner questioned using a projected trend when the actual trend is available and, in their view, has served the program well.[248] In its June 2022 Report to the Congress, MedPAC formally recommended the administratively set benchmarks approach.[249] In section III.G.7. of this proposed rule, we describe and seek comment on a potential longer-term approach for use of administratively set benchmarks that are decoupled from ongoing observed FFS spending.

Within this section of this proposed rule, we propose a combination of policies to ensure a robust benchmarking methodology that would reduce the effect of ACO performance on ACO historical benchmarks and increase options for ACOs caring for high-risk populations. Specifically, we are proposing to modify the methodology for updating the historical benchmark (section III.G.5.c.(3) of this proposed rule), incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs (section III.G.5.c.(4) of this proposed rule), and modify the negative regional adjustment (section III.G.5.c.(5) of this proposed rule). We also believe these proposed modifications could serve as ''stepping stones'' to a potential longer-term approach to the benchmarking methodology, and they are designed to be consistent with the potential approach for incorporating a methodology for administratively set benchmarks, which is described in the request for information in section III.G.7. of this proposed rule. In section III.G.5.c.(6) of this proposed rule we also seek comment on two potential alternatives to the package of policies we are proposing in sections III.G.5.c.(3) through (5). Both alternatives would seek to limit the impact of an ACO's own assigned beneficiaries on the regional factors used in benchmarking calculations. While these alternatives would address concerns raised by some interested parties, we believe they would be less effective than our

[244] Modifications to the risk adjustment methodology targeted at supporting ACO's serving medically complex, high cost populations are described in section III.G.5.e of this proposed rule. Modifications to participation options targeted at ACOs serving underserved populations, and providing a longer on-ramp to performance-based risk for certain ACOs are described in section III.G.2 of this propsed rule.

[245] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. *Health Affairs.* January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

[246] Serna L and Stensland J. MedPAC. Presentation on benchmark incentives for accountable care organizations (November 8, 2021), available at *https//www.medpac.gov/wp-content/uploads/2021/09/aco-benchmarks-medpac-nov-2021.pdf.*

[247] Burton R et al. MedPAC. Presentation on developing a multi-track population-based payment model with administratively updated benchmarks (January 14, 2022), available at *https://www.medpac.gov/wp-content/uploads/2021/10/APM-MedPAC-Jan22.pdf.*

[248] See, for example, Medicare Payment Advisory Commission, Public Meeting, Friday, January 14, 2022, transcript of proceedings starting at 10:02 am, available at *https://www.medpac.gov/wp-content/uploads/2021/10/Jan22_MedPAC_Meeting_Transcript_SEC.pdf* (refer to pages 166–246, enumerated pages 3–83).

[249] Medicare Payment Advisory Commission. June 2022 Report to the Congress: Medicare and the Health Care Delivery System (June 15, 2022), available at *https://www.medpac.gov/document/june-2022-report-to-the-congress-medicare-and-the-health-care-delivery-system/* (Chapter 1, pages 3–22).

proposed policies at addressing the full set of core concerns we articulate in this section.

(3) Incorporating a Prospective, External Factor in Growth Rates Used To Update the Historical Benchmark

(a) Background

As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. In accordance with § 425.601(b), for agreement periods beginning on July 1, 2019, and in subsequent years, we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year. To update the benchmark, we make separate calculations for expenditure categories for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid.

The national-regional blend is a weighted average of national FFS and regional growth rates between BY3 and the performance year for the applicable Medicare enrollment type. The national growth rates are computed using CMS OACT national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries (as defined at § 425.20) identified for the 12-month calendar year corresponding to each year. Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year. To calculate regional expenditures, we determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year, and determine the ACO's regional expenditures as specified under § 425.601(c) and (d).

The national and regional growth rates are blended together by taking a weighted average of the two. The weight assigned to the national component of the national-regional blend for a given Medicare enrollment type is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year, calculated by taking a weighted average of county-level shares as specified in § 425.601(a)(5)(v). To calculate this share, we first calculate the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area for that Medicare enrollment type. We then weight the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries for that Medicare enrollment type. Next, we sum these weighted county-level shares for all counties in the ACO's regional service area for each Medicare enrollment type.

As an ACO's penetration in its region increases, a higher weight is placed on the national component of the national-regional blend and a lower weight on the regional component. The national and regional growth rates are blended together by taking a weighted average of the two. Specifically, for each Medicare enrollment type, the national-regional blended growth rate is equal to the sum of the following: (1) the growth rate for national assignable FFS expenditures for BY3 to the performance year multiplied by the weight assigned to the national component; and (2) the average growth rate for regional FFS expenditures for BY3 to the performance year based on the ACO's regional service area multiplied by the weight assigned to the regional component. In accordance with § 425.601(a)(5), we also use blended national-regional growth rates to trend forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars, making separate calculations for each Medicare enrollment type.

We summarize concerns with the current benchmarking approach in section III.G.5.c.(2) of this proposed rule. Specifically, ACOs and other interested parties have expressed concerns regarding the dynamic under which an ACO that reduces costs for its own assigned beneficiaries also reduces its average regional costs, resulting in a relatively lower benchmark for the ACO under the blended national-regional growth rates used to trend and update the ACO's historical benchmark. As echoed in public comments, ACOs and other interested parties have suggested that this dynamic particularly disadvantages ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas (see, for example, 86 FR 65296 through 65299).

(b) Proposed Revisions

We are proposing to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to here as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. Incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor. Because the ACPT would be prospectively set at the outset of an agreement period, any savings generated by ACOs during the agreement period would not be reflected in the ACPT. Accordingly, incorporation of the ACPT would allow for benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. By limiting the negative feedback of efforts by ACOs to slow spending growth on their own benchmarks, we believe the use of this three-way blend to update ACOs' benchmarks would incentivize both greater savings by ACOs and greater program participation. Because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, we also believe that this proposed change to the update methodology would help to address the concerns discussed in section III.G.5.c.(2) of this proposed rule regarding the disproportionate impact of an ACO's savings on the benchmark update for ACOs with high market share. We discuss this in greater detail elsewhere in this section.

We are not proposing to revise the methodology used to trend forward per capita expenditures from BY1 and BY2 to BY3, but would maintain the current two-way blend used in calculating the ACO's benchmark. Modifying the methodology for determining the update factor but not the trend factor means there would no longer be parity between these factors, but we believe this would be an appropriate departure from the approach we have maintained since the start of the program. The two-way blend used for trend factors would continue to reflect actual growth rates, which we believe is still appropriate for purposes of determining the historical benchmark

because the benchmark is intended to reflect historical spending prior to any savings achieved during the agreement period for which the benchmark will be used. In contrast, the proposal to use a three-way blend to update the benchmark would incorporate a projected growth rate, the ACPT, which would reflect increases in spending independent of any savings achieved by the ACO, or ACOs collectively, during the agreement period, thus limiting the extent to which ACOs' success in reducing expenditures for their assigned beneficiaries over the course of an agreement period negatively impacts their ability to share in savings during that agreement period. We believe this would incent ACOs to reduce expenditures during the agreement period because there would be less risk of those reductions negatively impacting their benchmark updates. This, in turn, could lead to greater savings generated and increased shared savings payments to ACOs.

Under the proposed approach, a three-way blend would be calculated as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between BY3 and the performance year (PY). The ACPT component of the blend would be an external factor, meaning it would not be impacted by the individual or collective performance of ACOs. Within this proposed rule, reference to a ''two-way blend'' is synonymous with the existing blended national-regional growth rates under § 425.601.

The CMS Office of the Actuary (OACT) provides projections of Medicare program spending for various recurring deliverables, including the Medicare Trustees Report and the Advance Notice and Announcement of Medicare Advantage capitation rates and Part C and Part D payment policies. These publications include both historical and projected future Medicare spending amounts expressed on a per capita basis (differences in ESRD and non-ESRD calculations, are described in further detail in this section). These amounts published in the Advance Notice and the Announcement are labeled the FFS USPCCs. We are proposing to calculate the ACPT component of the blended annual update using an annualized growth rate based on 5-year-projections in per capita spending as of the start of an ACO's agreement period. We selected this projection horizon to align with the 5-year agreement periods used under the Shared Savings Program. The ACPT would be projected by OACT and would be a modification of the existing FFS USPCC growth trend projections used annually for establishing Medicare Advantage rates. The modifications to the FFS USPCC, aimed at making the trends more consistent with Shared Savings Program's existing expenditure calculations, would reflect the following:

- Exclusion of payments for indirect medical education (IME), disproportionate share hospitals (DSH), including both empirically justified DSH payments and uncompensated care payments, and the proposed new supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico, if finalized in the FY 2023 IPPS/LTCH PPS final rule.
- Inclusion of payments associated with hospice claims.

OACT currently produces separate FFS USPCCs for ESRD (dialysis-only, including aged/ESRD, disabled/ESRD and ESRD-only) and non-ESRD aged/disabled populations. Likewise, OACT would also calculate the ACPT separately for these two populations. Currently, most Shared Savings Program benchmarking calculations are performed separately for four separate Medicare enrollment types: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid. The Shared Savings Program identifies enrollment type status on a monthly basis. A beneficiary month is classified as an ESRD month if the beneficiary was in long-term dialysis or transplant status for that month (including up to 3 months post-graft). All non-ESRD months are then classified as one of the other three categories based on age (under 65 for disabled) and dual eligibility status (for beneficiaries 65 and over only).[250] We are proposing to use the ESRD ACPT in calculating update factors for the ESRD population and to use the combined Aged/Disabled ACPT in calculating update factors for the remaining three enrollment types (disabled, aged/dual eligible, aged/non-dual eligible). Using ACPTs based on the existing populations for which FFS USPCCs are calculated would allow us to leverage existing OACT models which do not currently differentiate among categories within the aged/disabled population. We do not believe that there would be significant precision gained from revising these existing models to incorporate assumptions regarding these distinctions. Furthermore, we note that outside of the unforeseen impact of the PHE for COVID-19, national assignable per capita spending growth rates were reasonably consistent across the three non-ESRD enrollment types from 2013–2019 and we anticipate that pattern continuing during the period in which the ACPT would be incorporated into ACO calculations.

We are proposing to set the ACPT growth factors for the ACO's entire 5-year agreement period near the start of the agreement period. The ACPT factors would remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs. We anticipate we would publish finalized ACPT values in the Spring of the first performance year of an ACO's agreement period, and we note earlier years' trends would be available for reference prior to the start of the ACO's agreement period. We acknowledge that, under an approach that sets the value of the ACPT at the start of an ACO's agreement period, ACOs entering agreement periods in different years could be subject to higher or lower updates depending on how projections change from year to year. This could lead ACOs to try to time their entry (or renewal) in the program to try to maximize the fixed portion of their update. However, we believe this concern will be mitigated because the ACPT would represent only one-third of the three-way blend used to update an ACO's benchmark.

We further propose that the annualized growth rate(s) would be calculated as either a uniform annualized projected growth rate over each of the 5 performance years of the 5-year agreement period, or as two or more annualized growth rates during the 5 performance years comprising the 5-year agreement period. Two or more annualized growth rates would be used if OACT determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve—for example, if growth is expected to be above- or below-average in the short-run and return to more typical levels later in the agreement period.

We considered whether the ACPT component of the blend should express projected growth on a relative basis (as the current two-way national-regional blend operates) or on an absolute (flat) dollar basis. Applying the new portion of the update as an absolute dollar growth amount would more closely adhere to the approach stipulated in section 1899(d)(1)(b)(ii) of the Act for the benchmark to be updated by the

[250] Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (January 2022, Version #10), available at *https://www.cms.gov/files/document/medicare-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1* (Appendix E).

projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. However, under the proposed approach, the ACPT would be weighted together with the two-way national-regional blend.

Based on retrospective modeling (described elsewhere in this section), both the relative basis and flat dollar approaches to calculating the ACPT are anticipated to improve the incentive to participate compared with the current two-way blend for both ACOs with higher market penetration within their regional service area (the ACO's assigned beneficiaries constitute at least 30 percent of the assignable beneficiary population within the ACO's regional service area) and ACOs operating in a regional service area with higher ACO market penetration (at least 50 percent of the assignable beneficiaries within an ACO's regional service area are assigned to any Shared Savings Program ACO). During the period examined, ACO benchmarks increased an average of $19 per capita, with an average of 62 percent of all ACOs across all years modeled receiving a larger benchmark increase compared with the current two-way blend. An average of 65 percent of ACOs operating in a regional service area with higher Shared Savings Program market penetration were better off under the three-way blended update factor compared with the current two-way blend. Additional results comparing the benefits of the three-way blend to the current two-way blend are described elsewhere in this section. We also anticipate that introducing the ACPT as part of a three-way blend may incentivize ACOs to achieve additional savings by providing a known prospective trend that allows for improved planning and provides a target for ACOs to compare their performance against. Because the prospective trend would allow ACOs to improve planning, a higher percentage of ACOs may benefit from the three-way blend than is reflected in the simulations. In addition, we expect the three-way blend would further insulate a portion of the benchmark update from the impact of an ACO's own savings, as actual spending trends downward from initial projections.

While both approaches are, on average, favorable for ACOs, the risk adjusted flat dollar approach is anticipated to be more beneficial to ACOs because the flat dollar amount would be based on per capita expenditures among the national assignable population, which tend to be higher than per capita expenditures among ACO-assigned beneficiaries. That is, if national per capita expenditures are projected to increase by 3 percent per year, a flat dollar amount representing 3 percent of per capita expenditures from the national assignable population would be greater than 3 percent of a typical ACO's own benchmark amount; thus, the flat dollar ACPT would result in a larger overall increase to the ACO's benchmark amount each year. Another potential advantage of calculating flat dollar amounts based on the national per capita FFS expenditures for the assignable population (rather than simply calculating flat dollar amounts from OACT's original projected dollar values for the ACPT), is that it allows us to generate separate values for each of the four Medicare enrollment types. This approach would also align projections with actual per capita expenditures of the assignable population, minimizing the degree to which the projections may systematically differ in how they are calculated.

Therefore, we are proposing to calculate flat dollar amounts (separately for each Medicare enrollment type) by applying the relevant projected growth rate to truncated national per capita FFS expenditures for assignable beneficiaries for BY3 for the given Medicare enrollment type. The assignable population for this calculation would be identified using the assignment window for the 12-month calendar year corresponding to BY3. Truncation would be done in the same manner as is done when calculating the ACO's own per capita expenditures to draw an equivalent comparison. That is, we would truncate national per capita FFS expenditures for assignable beneficiaries for BY3 for a given Medicare enrollment type, for purposes of calculating the ACPT flat dollar amounts, at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. This approach would be consistent with the approach to truncating an assigned beneficiary's expenditures in calculating the ACO's benchmark year expenditures as currently specified in § 425.601(a)(4), and in the proposed new provision at § 425.652(a)(4), and performance year expenditures as specified under § 425.605(a)(3) (BASIC track) and § 425.610(a)(4)(ii) (ENHANCED track). This approach to truncation to establish the ACPT flat dollar amounts would also align with the approach to truncating assignable beneficiary expenditures in calculating county expenditures (refer to § 425.601(c)(3), and the proposed new provision at § 425.654(a)(3)) used in determining factors based on regional FFS expenditures, including the regional component of the two-way blend.

We are further proposing to risk adjust these flat dollar amounts to account for differences in severity and case mix between the ACO's assigned beneficiaries and the national assignable FFS population for each Medicare enrollment type. We are concerned that flat dollar amounts that are not risk adjusted could generate a relatively lower update for higher spending ACOs caring for medically complex populations because the amount of the update would be set based on per capita expenditures for the national assignable population (which are likely to be lower) instead of the ACO's own assigned beneficiary population. Risk-adjusting the flat dollar amounts would provide a higher flat dollar amounts for ACOs serving medically complex populations. We are not proposing to adjust the ACPT flat dollar amounts for geographic differences in costs or prices, as we believe that such an adjustment may inadvertently reward higher spending, less efficient ACOs with a high market share in their regional service area.

In order to blend the risk adjusted flat dollar amounts with the corresponding two-way blend for each enrollment type, which would continue to operate on a relative basis, we would first need to re-express the risk adjusted flat dollar amounts on a relative basis by dividing by the ACO's historical benchmark expenditure amount. This would be done separately for each Medicare enrollment type.

Using hypothetical values, the steps below illustrate how we would set the annualized growth rate(s) and calculate the ACPT flat dollar amount(s) (re-expressed as a relative value) that would be included in the three-way blend.

Step 1: Calculate Annualized Growth Rate(s) for Agreement Period

For step 1, OACT would calculate one or more annualized growth rates for the ESRD population (the ESRD ACPT) and one or more annualized growth rates for the aged/disabled population (the Aged/Disabled ACPT). Specifically, for each population OACT would project per capita spending growth for Parts A and B Medicare FFS spending as described earlier in this section between BY3 and each performance year of the agreement period. These annualized growth rates may either be calculated as a uniform annualized projected rate of growth over each of the 5 performance years of the

5-year agreement period, or as two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period if CMS determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve.

Step 2: Express the Growth Rate(s) for Each Performance Year as Flat Dollar Amounts (the ACPT)

For step 2, we would multiply BY3 truncated national per capita FFS expenditures calculated by OACT for the assignable FFS population for a given enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries), by the applicable growth rate to calculate the flat dollar amount of growth for each performance year. As previously described in this section, we would use ESRD growth rate(s) for the ESRD population and non-ESRD aged/disabled growth rate(s) for the disabled, aged/dual eligible, and aged/non-dual eligible populations. Thus, for example, if the truncated national assignable per capita expenditures for a given enrollment type was $13,000, and the projected growth rate for that enrollment type in that year is 5 percent per year, the flat dollar amounts would be:

PY1 flat dollar amount = $13,000 × (1.050 − 1) = $650, and

PY5 flat dollar amount = $13,000 × (1.276 − 1) = $3,588 [251]

Step 3: Risk Adjust the Flat Dollar Amounts

In step 3, we would multiply the flat dollar amounts for each performance year, for each enrollment type, by the ACO's mean BY3 prospective HCC risk score [252] for that enrollment type. For consistency with other Shared Savings Program risk adjustment calculations, the risk score used would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Risk adjusting the flat dollar amounts would allow for a higher update for ACOs serving a population that is more medically complex than the national average. If the ACO's BY3 risk score was 1.025, the risk adjusted flat dollar amounts would be:

PY1 flat dollar amount = $650 × 1.025 = $666, and

PY5 flat dollar amount = $3,588 × 1.025 = $3,678

Step 4: Re-Express Risk Adjusted Flat Dollar Amounts as Relative Factors

The fourth and final step before calculating the three-way blended update factor would be to re-express the risk adjusted flat dollar amount for each enrollment type on a relative basis such that it can be combined in a weighted average with the current two-way blend. We would do this by dividing the risk adjusted flat dollar amounts computed in Step 3 for a given enrollment type by the ACO's historical benchmark expenditures for that enrollment type. The resulting amount would represent the final ACPT portion of the blended update factor for that enrollment type. If the historical benchmark expenditures for the enrollment type were $12,000, the final ACPT portion of the blended update factors for this enrollment type would be:

PY1 final ACPT portion of the blended update factor = ($666 / $12,000) + 1 = 1.056, and

PY5 final ACPT portion of the blended update factor = ($3,678 / $12,000) + 1 = 1.306

The values in this step would then be combined with the two-way blend to compute the three-way blended update factor. The ACPT would constitute one-third of the total blend, while the remaining two-thirds would consist of the existing two-way blend.

To illustrate how we would compute the three-way blend, and how it would compare with the two-way blend, assume for the same hypothetical ACO for a given enrollment type that the regional expenditure growth between BY3 and PY1 is 2.5 percent, that national assignable FFS expenditure growth is 3 percent and that the ACO's assigned beneficiaries represent 20 percent of the assignable population in the ACO's regional service area. For simplicity, assume the ACO faces a risk ratio of 1.0. The current two-way blended update factor would be calculated as:

Two-way blend = (National Update Factor × National Weight) [253] + (Regional Update Factor × (1 − National Weight)); or

Two-way blend = (1.030 × 20 percent) + (1.025 × 80 percent) = 1.026.

Updating the ACO's benchmark with the two-way blended update factor alone would yield a value of $12,312 (that is, $12,000 × 1.026 = $12,312).

To calculate the three-way blend by incorporating the PY1 ACPT factor of 1.056 (from earlier in the example) we would use the following weighted average:

Three-way blend = [PY1 ACPT × (1/3)] + [PY1 Two-Way Blend × (2/3)]; or

Three-way blend = [1.056 × (1/3)] + [1.026 × (2/3)] = 1.036.

Applying the three-way blended update factor to the historical benchmark would yield an updated benchmark of $12,432 for the enrollment type (that is, $12,000 × 1.036 = $12,432). In this example, the ACO's benchmark update factor increases by 1.0 percentage point, corresponding to an increase of $120 per capita, which increases the ACO's potential for shared savings and reduces the potential for shared losses, if applicable.

Including the ACPT as a component of a three-way blend could provide a degree of certainty that benchmarks would not be lowered as a result of ACOs reducing FFS spending growth, and thereby increase the incentive for such savings and strengthen incentives for ACOs to enter and remain in the Shared Savings Program. However, incorporating the ACPT into a three-way blended update factor would have the potential for mixed effects. For example, it may also lower an ACO's benchmark relative to the current approach if external factors lead to higher program spending growth than originally projected at the start of an ACO's agreement period. This could, for example, cause an ACO in a two-sided model that would not have been responsible for shared losses under the two-way blend to owe shared losses under the three-way blend or cause an ACO that would have owed shared losses under the two-way blend to owe a larger amount of shared losses under the three-way blend.

Additionally, the three-way blend could potentially have negative implications for an ACO based on the Shared Savings Program's policy regarding monitoring of ACO financial

[251] For a given performance year ''X'' in an agreement period, the growth rate is calculated by raising the annual growth rate to the power of X (that is, multiplying the annual growth rate by itself X times). Thus, for PY5 in this example, the annual growth rate of 1.276 is computed by raising 1.05 to the power of 5 (that is, multiplying the single year growth rate of 1.05 by itself 5 times).

[252] We have also used the terms ''CMS-HCC prospective risk scores'' and ''CMS-Hcc risk scores'' (see, for example, the December 2018 final rule, 83 FR 68007 through 68013) to refer to such risk scores. While we choose to use the term ''prospective HCC risk scores'' within this section of this proposed rule for consistency with terminology used in the regulations (see, for example, § § 425.601, 425.605, and 425.610), we consider these terms to be interchangeable.

[253] Weight for the national growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3 (refer to § 425.601(a)(5)(iv)(A)).

performance described in § 425.316(d). Under this policy, if an ACO's performance year expenditures exceed its updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model or the minimum loss rate (MLR) under a two-sided model, CMS may take pre-termination actions against the ACO. For a subsequent occurrence for another performance year in the same agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement.

Consequently, we believe a guardrail is needed to ensure the use of the three-way blend does not result in lower benchmarks than the current national-regional blend in a way that poses higher financial risk for ACOs under two-sided models, or that could jeopardize an ACO's continued participation in the Shared Savings Program under the financial performance monitoring policy described in § 425.316(d), or both.

We propose to institute this guardrail as follows: if an ACO generates losses for a performance year that meet or exceed its minimum loss rate (MLR) (for two-sided model ACOs) or negative MSR (for one-sided model ACOs) under the three-way blend, we would recalculate the ACO's updated benchmark using the national-regional blended update factor (two-way blend). If the ACO generates a smaller amount of losses using the two-way blend, we would use this smaller amount to determine the ACO's responsibility for shared losses, if applicable, and in determining the ACO's financial performance for monitoring purposes under § 425.316(d). If the ACO generates saving using the two-way blend to update its benchmark but does not generate savings under the three-way blend, the ACO would neither be responsible for shared losses (if in a two-sided model) nor eligible for shared savings for the applicable performance year, even if the savings generated exceed the ACO's MSR. ACOs in these scenarios would publicly report their performance in accordance with § 425.308(b)(4) based on the recalculated amounts determined using the two-way blend. However, an ACO that generated savings under the two-way blend, but was not eligible to earn a shared savings payment, would be required to report zero shared savings for the performance year. We believe this guardrail would protect ACOs from the most negative potential outcomes of the proposed three-way blend, while still insulating the Trust Funds.

To illustrate how the guardrail would be applied, consider a second hypothetical ACO participating at Level E of the BASIC track for which the updated benchmark calculated using the three-way blend was $12,760. Assume that the ACO's per capita performance year expenditures were $12,980 and that the ACO had selected a symmetrical MSR/MLR of 1.5 percent. Using the three-way blend, the ACO would have per capita losses of −$220, or −1.7 percent of its updated benchmark which would be above ACO's selected MLR of −1.5 percent. Applying the fixed shared loss rate of 30 percent under Level E, the ACO would, in absence of the guardrail, be liable for shared losses (on a per capita basis) of −$66 and would face potential pre-termination actions or involuntary termination (depending on the ACO's financial performance in prior years of its agreement period). However, with the guardrail in place, we would re-assess the ACO's performance using the two-way blend. If the two-way blend produced an updated benchmark of $12,804, the ACO's new per capita losses amount would be −$176, or −1.4 percent of its updated benchmark which would be within the ACO's selected MLR of −1.5 percent. This ACO would therefore not be responsible for shared losses for the performance year and would not face any negative consequences under the financial performance monitoring policy. If the two-way blend instead produced an updated benchmark of $13,183, the ACO would have measured per capita savings of $203, or 1.54 percent of its updated benchmark. As previously explained, under the proposed approach, the ACO would no longer be responsible for shared losses nor face pre-termination action or termination based on its financial performance. However, although the savings amount would exceed the ACO's MSR of 1.5 percent, the ACO would not be eligible for shared savings under the proposed policy.

Under this proposal to set the ACPT for the duration of the ACO's agreement period, we would not adjust the ACPT due to external factors such as geographic price changes, efficiency discounts, or other retrospective updates occurring during the performance years throughout the agreement period. However, we acknowledge that a variety of circumstances could cause actual expenditure trends to significantly deviate from projections. Thus, we believe there are circumstances that may warrant reducing the weight placed on the ACPT on an ad hoc basis. In particular, if we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered. For example, based on a review of projections detailed in the 2009 Medicare Trustees Report, an ACPT projected in 2009 (amidst the great recession and before passage of the ACA) would have ultimately overstated per capita spending growth from 2008 to 2013 by roughly 9 percentage points (which would have corresponded to a 3 percent upward bias to benchmarks when weighted as one-third of the blended update). We are especially concerned that such unforeseen circumstances could result in an update factor that significantly differs from actual expenditure trends, and in turn could result in ACOs owing excessive shared losses or the Medicare Trust Funds paying out windfall shared savings. As discussed elsewhere in this section, we are proposing a ''guardrail'' to provide protection for ACOs that would be responsible for sharing losses with the Medicare program based on an updated benchmark computed using the proposed three-way blend and that would have had a higher updated benchmark under the two-way blend. While we believe the guardrail offers protection against some unexpected variances between the projected amount and actual expenditures to protect against shared losses, we believe it is also important for CMS to retain flexibility to reduce the impact the prospectively determined ACPT portion of the three-way blend if unforeseen circumstances occur during an ACO's agreement period.

When determining an approach for adjusting the three-way blend if unforeseen circumstances occur, we considered CMS' experience with use of a prospective trend, calculated by OACT based on an adjusted USPCC amount, in the Next Generation ACO (NGACO) Model.[254] CMS maintained the sole discretion to retrospectively modify the projected trend used in calculating the performance year benchmark (aggregate expenditure target) if CMS determined that exogenous factors, such as a natural disaster, epidemiological event, legislative change and/or other similarly unforeseen circumstance during the performance year, rendered the projected trend invalid. CMS used this

[254] CMS, ''Next Generation ACO Model, Calculation of the Performance Year Benchmark: Performance Year 2021'' (Section 2.1.7, ''Prospective Base Year Trend''), available at *https://innovation.cms.gov/media/document/ngaco-py6-bnechmark-meth.*

discretion for the NGACO Model in response to the COVID-19 pandemic in performance years 2020 and 2021. For performance year 2020, instead of applying the prospective trend, CMS offered NGACOs the choice between use of a retrospective national trend or a retrospective regional trend. For performance year 2021, CMS applied a retrospective national trend to all NGACOs instead of a prospective trend.[255]

Based on the experience in the NGACO Model, we believe it would be appropriate, when unforeseen circumstances occur, to adjust the three-way blend to prevent drastic differences between actual and projected expenditure trends. Accordingly, we are proposing that if unforeseen circumstances occur, we would retain discretion to decrease the weight applied to the ACPT in the three-way blend. Absent unforeseen circumstances, we would weight the two-way blend as two-thirds and the ACPT as one-third in calculating the three-way blend. However, if CMS determines an unforeseen circumstance has occurred that would warrant adjustments to these weights, then CMS would modify the three-way blend to reduce the weight that will apply to the ACPT and increase the weight of the two-way blend. We further propose that CMS would have sole discretion to determine whether unforeseen circumstances exist that would warrant adjustments to these weights, as well as the extent to which the components of the three-way blend would be re-weighted. However, given that external factors that cause deviations from projected trends would continue to be reflected in the two-way blend component of the update factor, the impacts from unforeseen circumstances that either increase or decrease the two-way blend component would also then increase or decrease the three-way blend. This would likely mitigate the need to adjust the weight of the ACPT used in the three-way blend.

Based on initial modeling, we believe that the proposed three-way blended update factor with the associated guardrail, in combination with other benchmarking changes discussed elsewhere in section III.G.5.c. of this proposed rule, to apply a prior savings adjustment and mitigate the impact of negative regional adjustments on ACOs, would serve as a mid-term solution to ensuring the sustainability of ACOs' historical benchmarks as we consider moving toward an administrative benchmarking methodology, as discussed in section III.G.7. of this proposed rule.

To simulate the potential impact of the three-way blend, we examined ACO spending over a 5-year period (2014 to 2019) using ACO participant lists in effect for all 12- or 6-month performance years or performance periods beginning on January 1, 2019, and existing Medicare Part A and Part B USPCC projections published in the 2014 Medicare Trustees report.[256] We also adjusted the Part A projections to remove IME, DSH, and uncompensated care payments, to better reflect how the proposed ACPT would be calculated in practice. For the purposes of this simulation, we used 2014 per capita spending as the historical benchmark for each ACO in lieu of a 3-year base period. We then simulated updating each ACO's historical benchmark for each of the 5 subsequent years using the existing two-way blended update factor methodology (in accordance with § 425.601(b)) and incorporating the simulated flat dollar ACPT amounts into a three-way blended updated factor. We compared the simulated benchmark updates determined using this three-way blend to updates simulated using the existing two-way blend. These simulations showed that, on average, ACOs were better off over the course of the 5-year agreement period using the three-way blend than using the current two-way blend. That is, in a given year, an ACO's benchmark on average increased more when the annual update was calculated using the proposed three-way blend. Incorporating the ACPT into a three-way blended update factor during the model period resulted in an average benchmark increase of $19 per capita, with an average of 62 percent of all ACOs across all years modeled receiving a larger benchmark increase compared with the current two-way blend. ACOs with high market penetration within their regional service area (ACOs whose assigned beneficiaries constitute at least 30 percent of the assignable beneficiary population within the ACO's regional service area) had similar results to those with lower market penetration (61 percent vs 63 percent, respectively), with both groups receiving larger benchmark increases from the three-way blend. ACOs operating in markets where the Shared Savings Program as a whole has higher penetration (at least 50 percent of the assignable beneficiaries in an ACO's regional service area are assigned to any Shared Savings Program ACO) were, on average, better off under the three-way blend. We observed that, on average over the 5-year period used in our modeling, approximately 65 percent of ACOs operating in markets with high Shared Savings Program penetration had a larger benchmark increase under the three-way blend compared with the two-way blend. Additionally, an average of 50 percent of ACOs with at least 25 percent of assigned beneficiaries being dually eligible for Medicare and Medicaid received a higher benchmark update under the three-way blend as well as 65 percent of ACOs with at least 20 percent of assigned beneficiaries being disabled and 55 percent of ACOs operating in rural areas. As discussed elsewhere in this section, these results simulate a change in how the benchmark update is calculated holding everything else constant. That is, these results do not reflect any additional savings that may have materialized had a three-way blend that includes the ACPT been in place during the 5-year period included in our modeling. We anticipate that introducing the ACPT into a three-way blend may incentivize ACOs to achieve additional savings, and that the three-way blend would then insulate a portion of the benchmark update from the impact of those savings as actual spending trends downward from initial projections. As a result, a higher percentage of ACOs may benefit from the three-way blend than is reflected in these simulations.

We believe that incorporating the prospective trend into the benchmarking methodology by including the ACPT in a three-way blended update factor would be an important step towards an administrative benchmarking approach. ACOs may have a greater incentive to enter and continue participation in the Shared Savings Program when their benchmarks are further decoupled from their ongoing observed FFS spending while continuing to reflect a measure of the ACO's efficiency relative to its region. This approach may also serve to anchor and stabilize benchmarks to the extent that the ACPT projected growth component is an effective counterbalance when there are changes in an ACO's penetration in its regional service area that affect the weights given

[255] CMS, ''Next Generation ACO Model: Frequently Asked Questions'' (May 2021), available at *http://innovation.cms.gov/media/document/ngaco-2021-faqs.* Refer to question 18.

[256] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'', available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2014.pdf.*

to the national and regional expenditure components of the current two-way blended update factor. However, we recognize that some interested parties may still have concerns and prefer a different approach to address impacts that may result from ACO market penetration. In section III.G.5.c.(6) of this proposed rule we seek comment on two potential alternatives to the package of policies we are proposing in this section and in sections III.G.5.c.(4) and (5). Both of the alternatives presented in section III.G.5.c.(6) would attempt to limit the impact of an ACO's own assigned beneficiaries on regional factors used in the benchmarking methodology.

Because the proposed three-way blended update factor would be used in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act, this proposal would require us to continue to use our authority under section 1899(i)(3) of the Act. This provision grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model.

By combining an external, prospective factor calculated based on the USPCC, as a component in the benchmark update, we believe that the proposed ACPT/national-regional three-way blended update factor would decouple an ACO's benchmark to a certain degree from ongoing observed FFS spending which is currently reflected in ACO benchmarks under the methodology specified under § 425.601. This approach may serve to anchor and stabilize benchmarks to the extent that the ACPT projected growth component is an effective counterbalance to the savings achieved by ACOs participating in the Shared Savings Program, which reduce the update factor under the current two-way national-regional blended update, including as a result of increasing market penetration by efficient ACOs in their regional service area. The proposed guardrail is designed to protect ACOs from larger shared losses (or potentially from the negative implications of financial monitoring) but would not allow ACOs to move to a position of sharing in savings. Additionally, the proposal that CMS would retain discretion to reweight the components of the three-way blend to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances that result in drastic differences between the ACPT and actual national per capita FFS expenditure growth for assignable beneficiaries for a given performance year, would protect against ACOs owing excessive shared losses or the Medicare Trust Funds paying out windfall shared savings. We believe this combination of additional incentives and safeguards may encourage ACOs to enter and continue participation in the Shared Savings Program.

As discussed in section III.G.5.d. of this proposed rule, we are also proposing to determine the assignable population of beneficiaries used in calculating county-level FFS expenditures, and in other factors based on the assignable population in the ACO's regional service area, using the assignment window that corresponds to the ACO's selected assignment methodology to improve the precision of the calculations. This modification would address a favorable bias in calculations for ACOs under prospective assignment, resulting in an estimated decrease in regionally adjusted historical benchmarks for these ACOs estimated to range from 0.2 percent–1.9 percent based on modeling using historical benchmarks for ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019 (compared to leaving the bias uncorrected). If left uncorrected, the bias could potentially grow over time as more ACOs are subject to higher weights in the calculation of the regional adjustment. The proposed change in methodology for identifying the assignable beneficiaries used in calculating factors based on regional FFS expenditures would also improve the precision of the calculation of the blended national-regional growth rates within the benchmark update.

Considering the combination of these factors, we believe the changes to the methodology for updating the benchmark that we are proposing pursuant to section 1899(i)(3) of the Act would improve the quality and efficiency of items and services furnished under the Medicare Program. More specifically, we believe that the introduction of the prospectively set ACPT into the blended benchmark update factor would increase the incentive for ACOs to achieve savings by partially insulating ACOs from the impact of those savings on future benchmark updates. We also believe that this change would encourage ACOs to enter and remain in the Shared Savings Program, which would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs have an incentive to perform well on quality measures in order to maximize the shared savings they may receive, and in the case of ACOs participating under the ENHANCED track to minimize any shared losses owed (as described in section III.G.4. of this proposed rule). In addition, as discussed in the Regulatory Impact Analysis (section VII of this proposed rule), we project that this proposed approach for use of an ACPT/national-regional three-way blended update factor, in combination with other changes to the statutory payment model proposed elsewhere in this proposed rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, would not increase program expenditures relative to those under the statutory payment model. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We propose that the update factor based on a three-way blend of the ACPT and blended national-regional growth rates and the associated guardrail would be applicable to agreement periods beginning on January 1, 2024, and in subsequent years. The use of the three-way blend, the associated guardrail, and the discretion for CMS to adjust the weight of the ACPT in the three-way blend in the event of unforeseen circumstances would be specified in paragraph (b) of a proposed new provision at § 425.652, which would govern the process for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. We also propose to specify within § 425.652(b) the other components of the update factor, namely the calculation of the national and regional components of the blend which would follow the same approach currently specified under § 425.601(b), although

with conforming changes to reflect the use of a three-way blend. Further, we propose to specify the calculation of the ACPT in a new provision at § 425.660. Refer to section III.G.5.i. of this proposed rule for a discussion of the organization of the proposed new provisions in 42 CFR part 425, subpart G.

We seek comment on the proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. We also seek comment on the specific elements of this approach, including our proposal to calculate the ACPT on a risk adjusted flat dollar basis, to institute a guardrail to protect ACOs, and to retain discretion to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances.

(4) Adjusting ACO Benchmarks To Account for Prior Savings

(a) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment that applied when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2016, to account for the average per capita amount of savings generated during the ACO's prior agreement period.[257]

The prior savings adjustment adopted in the June 2015 final rule (80 FR 32788 through 32791) was designed to adjust an ACO's benchmark for its second agreement period to account for the average per capita amount of savings generated by the ACO across the 3 performance years of its first agreement period. This average per capita amount also accounted for the ACO's quality performance in each performance year under its first agreement period. We limited the adjustment to the benchmark for the second agreement period to the average number of assigned beneficiaries (expressed as person years)[258] under the ACO's first agreement period in order to help ensure that the adjustment did not exceed the amount of net savings generated by the ACO during the first agreement period due to ACO participant list changes that may increase the number of assigned beneficiaries in the second agreement period (80 FR 32789). In calculating the adjustment, we used data from the ACO's finalized financial reconciliation reports for the performance years which corresponded to the benchmark years for the ACO's second agreement period. As described in the June 2015 final rule, the calculation included the following steps (80 FR 32789):

- *Step 1:* Determine whether the ACO generated net savings. For each performance year we determined an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. However, the ACO's total updated benchmark expenditures minus total performance year expenditures could not exceed the performance payment limit for the relevant track. If the sum of the per capita amounts for the 3 performance years was positive, the ACO would be determined to have net savings and we would proceed with Steps 2 and 3. If the sum of the per capita amounts for the 3 performance years was zero or negative, we did not make any adjustment to the ACO's rebased benchmark to account for any savings the ACO may have generated under its prior agreement period.
- *Step 2:* Calculate an average per capita amount of savings reflecting the ACO's final sharing rates based on quality performance. We averaged the performance year per capita amounts determined in Step 1 to determine the average per capita amount for the agreement period. We also determined the ACO's average final sharing rate, based on an average of the ACO's quality performance in each performance year of the agreement period. Therefore, the average per capita amount of savings would account for those situations where an ACO's sharing rate for a performance year was set equal to zero (based on the ACO's failure to meet the quality performance requirements in that year). We then calculated an average per capita amount of savings which was the product of the average performance year per capita amount and the average sharing rate based on quality performance.
- *Step 3:* Add the average per capita amount of savings determined in Step 2 to the ACO's rebased historical benchmark. The additional per capita amount was applied to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period.

Reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology as described in section III.G.5.c.(2) of this proposed rule. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. Furthermore, we believe that returning dollar value to benchmarks through a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark. We also note that when applying two adjustments in establishing the benchmark—a prior savings adjustment and a regional adjustment—there are number of considerations related to the potential interactions between these adjustments. These interactions will determine the extent to which efficient ACOs receive positive regional adjustments to their benchmark and the extent to which less efficient ACOs can use their savings from a prior agreement period to offset a negative regional adjustment, which could help foster their continued participation in the Shared Savings Program.

(b) Proposed Revisions

We are proposing to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024,

[257] The relevant provision was originally finalized at § 425.602(c) in the June 2015 final rule (80 FR 32842). In the June 2016 final rule, we removed paragraph (c) from § 425.602 and included this provision within paragraph (b) of § 425.603 (81 FR 37968, 38014).

[258] To calculate person years: We sum the number of Shared Savings Program-eligible months for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, February 2022), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1* (Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

and in subsequent years and that were reconciled for one or more of the 3 performance years immediately preceding the start of their agreement period. We considered a variety of approaches to calculating the prior savings adjustment and prefer an approach that resembles the policy implemented for renewing ACOs entering a second agreement period in 2016 but that includes additional steps to account for subsequent changes in Shared Savings Program policies. Specifically, these steps would account for the impact of the regional adjustment on the ACO's benchmark and attribute prior savings to re-entering ACOs.[259]

In the June 2016 final rule (81 FR 37962 through 37965), we explained our belief that it was important to forgo the adjustment to account for shared savings generated by the ACO under its prior agreement period when transitioning to a benchmark rebasing methodology that incorporates an adjustment for regional FFS expenditures. We anticipated that for ACOs generating savings, a rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO's rebased benchmark for its subsequent agreement period. At the time, we disagreed with comments suggesting that we either maintain the adjustment for prior savings or broaden its scope to make it more generous because we believed that maintaining an adjustment for prior savings alongside a regional adjustment could allow benchmarks to become overly inflated for some ACOs (particularly those benefiting from the regional adjustment). We also believed that continued application of the adjustment for prior savings would further tie an ACO's benchmark to its past performance rather than making it more reflective of FFS spending in the ACO's region, which was an important aim of revisions to the rebasing methodology in the June 2016 final rule (81 FR 37965).

Based on our experience with rebasing under the current benchmarking methodology, we now believe it would be timely to re-introduce a prior savings adjustment to ensure rebased benchmarks continue to serve as a reasonable baseline when benchmark years correspond to performance years of the ACO's preceding agreement period. However, we continue to believe that the rebased benchmarks of ACOs that are lower spending compared to their regional service area and that generated savings in their benchmark years could become overinflated if we were to allow for both a prior savings adjustment and a positive regional adjustment. To prevent this from occurring, we believe that adjusting an ACO's benchmark based on the higher of either the prior saving adjustment or the ACO's positive regional adjustment would be appropriate.

Additionally, we believe it would be appropriate to use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. This would permit ACOs that have generated savings in prior years to receive a relatively higher benchmark than under the current approach, which would incorporate a negative regional adjustment. We recognize that there are interactions between this proposed approach and the proposal to reduce the amount of the negative regional adjustment described in section III.G.5.c.(5) of this proposed rule. We have accounted for these interactions in developing the proposed methodology for determining the prior savings adjustment.

In order to calculate the prior savings adjustment, we propose calculating the simple average of per capita savings or losses generated by the ACO during the 3 performance years that immediately precede the start of the ACO's current agreement period, and therefore, constitute the benchmark years of the current agreement period. The per capita savings for each performance year would be determined as the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. We would use all savings generated during each of the prior 3 performance years in the prior savings adjustment, not just savings that met or exceeded the ACO's MSR for that prior performance year. This would include savings generated by ACOs that were participating in an agreement period under the BASIC track that did not meet the MSR but met the expanded criteria to qualify for shared savings as proposed in section III.G.5.f. of this proposed rule. An ACO would be eligible for the prior savings adjustment if the ACO generates positive average prior savings across the 3 performance years immediately preceding the start of its current agreement period. If an ACO is not eligible to receive a prior savings adjustment, the ACO would receive the regional adjustment to its benchmark.

In calculating an ACO's average per capita prior savings over the 3 performance years immediately preceding the start of its agreement period, we believe a safeguard is needed to ensure that ACOs that achieved savings for a performance year that serves as a benchmark year for the current agreement period, but were ineligible to receive a shared savings payment due to noncompliance with Shared Savings Program requirements, are not subsequently eligible to have a portion of those savings included in their historical benchmark. Without such a safeguard, we would be rewarding an ACO, despite its noncompliance, through a higher benchmark in its subsequent agreement period. This would conflict with the sanction imposed on the ACO for its noncompliance during the performance year(s) of its prior agreement period. Accordingly, we propose that if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements, we would set at zero the per capita amount of savings for the affected performance year(s) when calculating the prior savings adjustment.

There are a variety of reasons that could result in an ACO's ineligibility to receive a shared savings payment due to noncompliance. In accordance with §§ 425.605(c)(2), and 425.610(c)(2), an ACO does not qualify to receive shared savings for a performance year if it failed to meet the quality performance standard as specified under § 425.512 (also refer to section III.G.4.b. of this proposed rule for proposed modifications to the use of quality performance in determining shared savings and shared losses) or otherwise did not maintain its eligibility to participate in the Shared Savings Program. Furthermore, an ACO is not eligible to receive shared savings during the time it is under a corrective action plan (CAP) for avoidance of at-risk beneficiaries, or for performance years attributable to the time that necessitated the CAP (§ 425.316(b)(2)(ii)).

[259] According to § 425.20, re-entering ACO means an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions: (1) Is the same legal entity as an ACO, as defined according to § 425.20, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—(i) An ACO whose participation agreement expired without having been renewed; or (ii) An ACO whose participation agreement was terminated under §§ 425.218 or 425.220. (2) Is a new legal entity that has never participate in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

We propose to apply a prior savings adjustment in establishing the historical benchmark for re-entering ACOs that meet the eligibility criteria for the adjustment. Under § 425.20, a re-entering ACO means an ACO that is not a renewing ACO and that is either the same legal entity as an ACO that previously participated in the program or a new legal entity that has never participated in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118 of the same ACO in any of the 5 most recent performance years prior to the agreement start date. For new ACOs that are identified as a re-entering ACO, we propose to calculate the average per capita prior savings based on the prior performance of the ACO in which 50 percent or more the ACO participants previously participated. We attribute various aspects of this prior ACO to the re-entering ACO for purposes of determining its eligibility to participate in the Shared Savings Program (§ 425.224), and to determine the agreement period the ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods (§ 425.600(f)). We believe it would also be appropriate to attribute to the re-entering ACO the prior savings of this prior ACO. Therefore, in calculating the average per capita prior savings for ACOs identified as re-entering ACOs, we would include the per capita savings or losses of the prior ACO in the 3 performance years immediately preceding the start of the re-entering ACO's agreement period. This calculation would exclude from the prior savings adjustment any savings generated for performance years in which the prior ACO was ineligible to share in savings because of noncompliance with Shared Savings Program requirements. This safeguard would help to ensure that we are not rewarding ACOs for circumstances that may have led to their termination from the program, including circumstances that may have led to the formation of a new ACO.

We propose to apply a proration factor to the prior savings adjustment to account for situations where an ACO's assigned beneficiary population is larger in the benchmark years when calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year, than the ACO's assigned beneficiary population was when the ACO was reconciled for the 3 performance years preceding the start of its current agreement period. Although the proration approach was not described with much specificity in the earlier rulemaking, this proration factor would be calculated and implemented in a manner that is mathematically equivalent to the cap on the prior savings adjustment that was adopted in the June 2015 final rule (80 FR 32789).

Mathematically, to apply this proration factor we would calculate a ratio between: (1) the ACO's average person years for the 3 performance years that constitute the benchmark years for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods) and (2) the average person years in the 3 benchmark years for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year. Increases in beneficiary assignment would therefore result in a ratio less than 1, while decreases in assignment would result in a ratio greater than 1. This ratio would be capped at 1 to avoid increasing the per capita prior savings adjustment if the average number of beneficiaries assigned to the ACO across the 3 benchmark years of its current agreement period is lower than the average number of beneficiaries assigned during the 3 performance years immediately preceding the start of the ACO's current agreement period. This proration factor would be multiplied by the average positive per capita prior savings for the 3 performance years immediately preceding the start of the ACO's current agreement period to produce the pro-rated average per capita prior savings. Prorating for growth in assignment would ensure that the prior savings adjustment does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute the benchmark years for its current agreement period.

We note that there are a number of factors affecting the size of the ACO's assigned population between when CMS determined assignment for the performance year under the prior agreement period, and when CMS determines assignment for the corresponding benchmark year of the ACO's current agreement period, thereby necessitating the calculation of the proration factor at the start of the ACO's new agreement period. Specifically, changes in the size of the ACO's assigned beneficiary population could be due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E. These circumstances also could arise during the course of an ACO's agreement period, and thereby also affect benchmark year assignment. Therefore, for the second and each subsequent performance year during the term of the current agreement period, we propose to redetermine this proration factor under § 425.652(a)(9)(iv) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period, for the aforementioned reasons.

We further propose to account for circumstances when an ACO was not reconciled for one or more of the 3 performance years immediately preceding the start of its current agreement period in the calculation of average per capita prior savings and the proration factor. ACOs that renew their agreement periods early or are a re-entering ACO may not be reconciled for one or more of the 3 years preceding the start of their current agreement period depending upon the timing of the expiration or termination of their prior agreement period and the start of their new agreement period. We propose that if an ACO (or the prior ACO, if the ACO is identified as a re-entering ACO) was not reconciled during any of the 3 performance years immediately preceding the start of its current agreement period, the ACO would receive zero savings or losses in the calculation of average per capita prior savings for the relevant year(s). We believe this is appropriate because the purpose of the prior savings adjustment is to return to an ACO's benchmark a portion of the savings experienced by beneficiaries assigned to the ACO during the 3 performance years immediately preceding the start of its current agreement period and CMS has no way to determine whether the ACO would have generated savings or losses during performance years it was not reconciled for. Excluding these years entirely from the calculation of average per capita prior savings would unduly increase the weight on the other year(s) included in the prior savings adjustment calculation for which the ACO received financial reconciliation results.

In contrast, we believe it would be appropriate to exclude years the ACO (or the prior ACO, if the ACO is identified as a re-entering ACO) was not reconciled for when calculating the proration factor. The purpose of the proration factor is to account for

situations where an ACO's assigned beneficiary population calculated at financial reconciliation in the 3 years preceding the start of the ACO's agreement period (numerator) is smaller than the ACO's assigned beneficiary population identified for those same years using the ACO's certified ACO participant list and assignment methodology for the current performance year (denominator).

If an ACO was not reconciled for one or more of the 3 performance years immediately preceding the start of its current agreement period, it would naturally have zero assigned beneficiaries determined at financial reconciliation for such years, which would factor into the numerator of the proration factor if such years were considered. However, the ACO would have positive beneficiary counts in the 3 years preceding the start of its current agreement period generated using the ACO's certified ACO participant list and assignment methodology for the current performance year, which would factor into the denominator of the proration factor if such years were considered. Thus, if the numerator and the denominator were both calculated as averages over 3 years, incorporating years for which the ACO was not reconciled in the calculation of the proration factor would artificially decrease the proration factor and lead to a smaller pro-rated average per capita prior savings for the ACO. Alternatively, if the numerator were calculated as an average that excludes performance years for which the ACO was not reconciled (that is, as an average across less than 3 years, including only those years an ACO was reconciled for) and the denominator was calculated as an average that included all 3 years preceding the beginning of the ACO's agreement period, the direction of the impact on the proration factor would depend on whether the number of assigned beneficiaries calculated using an ACO's current certified ACO participant list and assignment methodology in the benchmark years for which the ACO was not reconciled exceeds the number of assigned beneficiaries in the other benchmark years, and by how much. Therefore, we see no compelling reason to include any of the 3 performance years immediately preceding the start of an ACO's agreement period for which the ACO was not reconciled in the numerator or the denominator of the proration factor and propose to remove such years from the calculation of the proration factor. This would ensure that the proration factor compares average person years determined for prior performance years at financial reconciliation (numerator) to average person years determined using the ACO's current certified ACO participant list and assignment methodology (denominator) across a consistent set of years preceding the start of the ACO's agreement period.

For instance, if an ACO were only reconciled in 2 of the 3 performance years immediately preceding the start of its current agreement period, the proration factor would be calculated as a ratio between: (1) the ACO's average person years for the 2 performance years for which the ACO was reconciled (regardless of whether these performance years occurred over one or multiple prior agreement periods) and (2) the average person years in the 2 benchmark years of the ACO's current agreement period which correspond to these same 2 performance years, calculated using the ACO's certified ACO participant list and assignment methodology for the current performance year. Tables 55 and 56 provide examples of the proration factor calculation when an ACO was not reconciled for one of the 3 performance years preceding the start of its agreement period. We do not propose parallel adjustments to the calculation of the proration factor if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements. We believe this is appropriate because if an ACO was ineligible to share in savings in one of these years due to a noncompliance issue, we could still use the ACO's assigned person years calculated at financial reconciliation in each of the 3 years preceding the start of the ACO's agreement period in the numerator of the proration factor, and could calculate the proration factor using the same method we would use for other ACOs that were reconciled in each of the 3 performance years immediately preceding the beginning of its agreement period.

We propose to calculate the final prior savings adjustment separately depending on whether an ACO is higher or lower spending relative to its regional service area. In order to avoid overinflating the benchmarks of ACOs that are lower spending relative to their regional service area by granting them both a prior savings adjustment and a positive regional adjustment, we believe it would be appropriate to apply the higher of the prior savings adjustment and the regional adjustment. In contrast, for ACOs that are higher spending relative to their region, we believe it would be appropriate to apply the prior savings adjustment to offset their negative regional adjustments partially or in full.

For an ACO that is lower spending than its regional service area, we propose that the ACO would receive an adjustment equal to the higher of the following: (1) its positive regional adjustment; and (2) a prior savings adjustment equal to the lesser of—(i) 50 percent of its pro-rated positive average per capita prior savings and (ii) 5 percent of national per capita FFS expenditures for assignable beneficiaries. The national assignable per capita FFS expenditure cap used in this calculation would be expressed as a single per capita value by weighting the national per capita FFS expenditure averages for assignable beneficiaries of each Medicare enrollment type according to the ACO's person-year based enrollment proportions. The regional adjustment used in this calculation would be the ACO's regional adjustment determined as specified in the proposed new provision at § 425.656 (which includes modifications to the methodology for determining the regional adjustment as proposed in section III.G.5.c.(5) of this proposed rule) and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values. We believe that the cap on the prior savings adjustment at 5 percent of national per capita FFS expenditures for assignable beneficiaries is needed to ensure the amount of the prior savings adjustment does not inflate an ACO's benchmark to the point where the ACO is likely to generate shared savings without decreasing expenditures. The cap at 5 percent of national per capita FFS expenditures for assignable beneficiaries would align with the existing cap on positive regional adjustments (see § 425.601(a)(8)(ii)(C)). Further we note that the 5 percent cap on regional adjustments is adjusted to exclude episodes of care for treatment of COVID–19 in accordance with § 425.611(c)(2)(iii). Consistent with this current approach, we propose to adjust the cap on prior savings adjustments to exclude episodes of care for treatment of COVID-19, and to specify this adjustment through modifications to the regulation at § 425.611(c)(2)(iii).

We are proposing to apply the 50 percent scaling factor to the pro-rated positive average per capita prior savings because we believe it is important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the

applicable performance years under its prior agreement period(s). The earlier version of the prior savings adjustment adopted in the June 2015 final rule also included a provision to scale the average per capita prior savings by a factor related to the sharing rate. Under this former policy, the ACO's average per capita prior savings were multiplied against its average final sharing rate across the prior agreement period. The average final sharing rate was determined using an average of the ACO's quality performance in each performance year of the prior agreement period (80 FR 32789). The proposed policy of applying a 50 percent scaling factor to the pro-rated positive average per capita prior savings is a simplification of the older approach. The sharing rates vary within the Shared Savings Program's tracks/levels. Within an ACO's agreement period under the BASIC track's glide path, differing sharing rates will apply depending on the ACO's level of participation. Under the BASIC track, the maximum sharing rate is 40 percent under one-sided model Levels A and B, and 50 percent under two-sided model Levels C, D, and E (§ 425.605(d)). Under the ENHANCED track the maximum sharing rate is 75 percent (§ 425.610(d)). We also note several proposals described elsewhere in this proposed rule would affect the sharing rates: the proposal to apply sharing rates not to exceed one-half of the maximum amount within each Level of the BASIC track for eligible low revenue ACOs (section III.G.5.f. of this proposed rule); and the proposal to use a sliding scale in determining shared savings based on the ACO's quality performance for ACOs that meet the proposed alternative quality performance standard (section III.G.4.b. of this proposed rule). For simplicity, we believe it would be appropriate to apply a consistent scaling factor in calculating the prior savings adjustment when an ACO is lower spending relative to its regional service area. We believe that a 50 percent scaling factor is appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track, and also takes into account the opportunity for ACOs to earn shared savings on a sliding scale under the proposed alternative quality performance standard.

For ACOs that are higher spending relative to their regional service area, we propose to calculate the final adjustment to the benchmark by adding the pro-rated average per capita prior savings to the ACO's negative regional adjustment calculated as proposed in section III.G.5.c.(5) of this proposed rule and in the proposed new regulation at § 425.656. If this sum is positive, we propose that the ACO would receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the positive sum and 5 percent of national per capita FFS expenditures for assignable beneficiaries. We are proposing to apply the 50 percent scaling factor to the positive sum of the ACO's regional adjustment and the pro-rated average per capita prior savings instead of to the total pro-rated average per capita savings in order to strengthen incentives for ACOs to remain in the program by increasing the portion of the pro-rated average per capita savings that is added to the regional adjustment in determining the final adjustment to the benchmark. The cap to the adjustment at 5 percent of national per capita FFS expenditures for assignable beneficiaries mirrors the proposed methodology described previously for determining the prior savings adjustment for ACOs with a positive regional adjustment. If the sum of the ACO's negative regional adjustment and its pro-rated average per capita prior savings is negative, the ACO would receive a reduced negative regional adjustment equal to the negative sum. In this case, the prior savings adjustment would not be subject to a 50 percent scaling factor because we believe that it would be appropriate to give the ACO the full benefit of generated prior savings when doing so would still not result in an overall positive adjustment to the benchmark that would be likely to inflate the ACO's benchmark. We believe this approach would also strengthen the incentive for ACOs that are higher spending than their regional service area to remain in the program and continue generating savings. We note we are also proposing to reduce the current 5 percent cap on negative regional adjustments to 1.5 percent (see section III.G.5.c.(5) of this proposed rule). If this proposal is finalized, the sum of the pro-rated average per capita prior savings and the negative regional adjustment would, necessarily, be less than 1.5 percent of national per capita FFS expenditures for assignable beneficiaries.

We propose to use the following steps to calculate the prior savings adjustment:

- *Step 1:* Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period. For each performance year we would determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS would apply the following requirements in determining the amount of per capita savings or losses for each performance year:

++ The per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.

++ If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with Shared Savings Program requirements, the per capita savings for that year would be set to zero.

++ For a new ACO that is identified as a re-entering ACO, per capita savings or losses would be determined based on the per capita savings or losses of the ACO in which the majority of the ACO participants in the re-entering ACO were participating.

- *Step 2:* Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS would use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

++ If the average per capita value is less than or equal to zero, the ACO would not be eligible for a prior savings adjustment. The ACO would receive the regional adjustment to its benchmark.

++ If the average per capita value is positive, the ACO would be eligible for a prior savings adjustment.

- *Step 3:* Apply a proration factor to the per capita savings calculated in Step 2 equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. If the ACO was not reconciled for one or more of the 3 years preceding the start of the ACO's current agreement period, the person years from that year (or years) would be excluded from the averages in the numerator and the denominator of this ratio. For a new ACO that is identified as a re-entering ACO, the person years of the ACO in which the majority of the ACO participants of the re-entering ACO were participating would be used in the numerator of the calculation. This ratio

would be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology.

• *Step 4:* Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment, determined as specified in the proposed new regulation at § 425.656, expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

++ If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings value and determine the final adjustment as follows:

—If the sum is positive, the ACO would receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment and 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment would be applied as a flat rate to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—If this sum is negative, this would constitute the amount of the negative regional adjustment applied to the ACO's historical benchmark. The adjustment would be applied as a flat dollar amount to the historical benchmark expenditures for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ If the regional adjustment, expressed as a single value, is positive, the ACO would receive an adjustment to the benchmark equal to the higher of the following:

—The positive regional adjustment amount. The adjustment would be applied separately to the historical benchmark expenditures for each of the following populations of beneficiaries according to the methodology for calculating the regional adjustment (as proposed under § 425.656(c)): ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings value and 5 percent of national per capita FFS expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment would be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

Note that an implication of using an ACO's prior performance to calculate the prior savings adjustment is that at the time we determine the preliminary historical benchmarks, an ACO entering a new agreement period that completed a performance year that corresponds to BY3 of its new agreement period will not have prior savings data yet available for that year. In this case, we anticipate completing financial reconciliation for that performance year midway through the first performance year of the ACO's new agreement period. Accordingly, to determine the preliminary historical benchmark for the first year of the ACO's new agreement period, we would calculate the prior savings adjustment using zero savings in BY3. We would then update the calculation at the time we calculate the ACO's final historical benchmark to incorporate any applicable BY3 savings. As a result, production and release of final historical benchmarks may need to be delayed until after the calculation and release of financial reconciliation results for the preceding performance year.

Tables 55 through 58 present hypothetical examples to demonstrate how the adjustment for prior savings would work in practice.

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TABLE 55: ACO with Negative Regional Adjustment, Sum of Regional Adjustment, and Pro-rated Average Prior Savings is Positive

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021 $0 (Not Reconciled) PY 2022: $1,400 PY 2023: $1,500
Step 2: Calculate Average Per Capita Prior Savings	($0 + $1,400 + $1,500) / 3 = $966.67
Step 3: Calculate and Apply Proration Factor	Assigned person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 0 (Not included in proration factor because ACO was not reconciled) PY 2022: 5,000 PY 2023: 7,000 Assigned person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 11,000 (Not included in proration factor because ACO was not reconciled) BY 2022 (BY2): 9,000 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period, excluding years for which the ACO was not reconciled [(5,000 + 7,000)/2] / [(9,000 + 7,000)/2] = 0.75, capped at 1 Proration factor = 0.75 Apply proration factor to average per capita prior savings: $966.67 x 0.75 = $725.00
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $-100 Sum of regional adjustment and pro-rated average per capita prior savings: -$100 + $725.00= $625.00 5 percent of national per capita FFS expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $625.00 x 50% and $600 = $312.50 Per capita benchmark expenditures after regional adjustment and prior savings adjustment: ESRD: $90,000 + $312.50= $90,312.50 Disabled: $13,000 + $312.50= $13,312.50 Aged/dual: $20,000 + $312.50= $20,312.50 Aged/non-dual: $11,000 + $312.50= $11,312.50

TABLE 56: ACO with Negative Regional Adjustment, Sum of Regional Adjustment, and Pro-rated Average Prior Savings is Negative

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: $0 (Not Reconciled) PY 2022: $250 PY 2023: $150
Step 2: Calculate Average Per Capita Prior Savings	($0 + $250 + $150) / 3 = $133.33
Step 3: Calculate and Apply Proration Factor	Assigned person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 0 (Not Included in proration factor because ACO was not reconciled) PY 2022: 6,000 PY 2023: 10,000 Assigned person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 8,000 (Not Included in proration factor because ACO was not reconciled) BY 2022 (BY2): 6,000 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period, excluding years for which the ACO was not reconciled [(6,000 + 10,000)/2] / [(6,000 + 7,000)/2] = 1.23, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $133.33 x 1 = $133.33
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $-150 Sum of regional adjustment and pro-rated average per capita prior savings: -$150 + $133.33= -$16.67 Final adjustment is -$16.67 Per capita benchmark expenditures after regional adjustment and prior savings adjustment: ESRD: $91,000 - $16.67 = $90,983.33 Disabled: $12,000 - $16.67 = $11,983.33 Aged/dual: $19,000 - $16.67 = $18,983.33 Aged/non-dual: $10,000 - $16.67 = $9,983.33

TABLE 57: ACO with Positive Regional Adjustment, ACO Receives Prior Savings Adjustment

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: -$100 PY 2022: $600 PY 2023: $900
Step 2: Calculate Average Per Capita Prior Savings	(-$100 + $600 + $900) / 3 = $466.67
Step 3: Calculate and Apply Proration Factor	Assigned person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 8,000 PY 2022: 7,000 PY 2023: 9,000 Assigned person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 6,000 BY 2022 (BY2): 5,500 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period [(8,000 + 7,000 + 9,000)/3] / [(6,000 +5,500 + 7,000)/3] = 1.30, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $466.67 x 1 = $466.67
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $50 5 percent of national per capita FFS assignable expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $466.67 x 50% and $600 = $233.34 Higher of regional adjustment and capped pro-rated average per capita prior savings: Higher of $50 and $233.34 = $233.34 Per capita benchmark expenditures after prior savings adjustment: ESRD: $92,000 + $233.34 = $92,233.34 Disabled: $13,000 + $233.34 = $13,233.34 Aged/dual: $19,000 + $233.34 = $19,233.34 Aged/non-dual: $10,000 + $233.34 = $10,233.34

TABLE 58: ACO with Positive Regional Adjustment, ACO Receives Regional Adjustment

Step 1: Identify Savings	Per capita savings generated in 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: -$100 PY 2022: $600 PY 2023: $900
Step 2: Calculate Average Per Capita Prior Savings	(-$100 + $600 + $900) / 3 = $466.67
Step 3: Calculate and Apply Proration Factor	Assigned person years from the 3 performance years that constitute benchmark years for the ACO's current agreement period: PY 2021: 8,000 PY 2022: 7,000 PY 2023: 9,000 Assigned person years for benchmark years of current agreement period (determined using certified ACO participant list for current performance year): BY 2021 (BY1): 6,000 BY 2022 (BY2): 5,500 BY 2023 (BY3): 7,000 Proration factor: Ratio between the ACO's average person years in the previous 3 performance years and the average person years in benchmark years for the ACO's current agreement period [(8,000 + 7,000 + 9,000)/3] / [(6,000 +5,500 + 7,000)/3] = 1.30, capped at 1 Proration factor = 1 Apply proration factor to average per capita prior savings: $466.67 x 1 = $466.67
Step 4: Determine Final Adjustment to Benchmark	Regional adjustment expressed as single per capita value: $250 5 percent of national per capita FFS expenditures for assignable beneficiaries: $600 Lesser of 50 percent of pro-rated average per capita prior savings and 5 percent of national per capita FFS expenditures for assignable beneficiaries (capped pro-rated average per capita prior savings): Lesser of $466.67 x 50% and $600 = $233.34 Higher of regional adjustment and capped pro-rated average per capita prior savings: Higher of $250 and $233.34 = $250 Per capita benchmark expenditures after regional adjustment: ESRD: $92,000 + $880= $92,880 Disabled: $13,000 + $310= $13,310 Aged/dual: $19,000 + $850= $19,850 Aged/non-dual: $10,000 + $200= $10,200

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We believe that incorporating an adjustment for prior savings, when the adjustment for prior savings would be more advantageous for ACOs than the regional adjustment, would limit the negative ratchet effects of benchmark rebasing. Under the existing benchmarking methodology, the savings an ACO achieves in one agreement period can reduce its rebased benchmark for the subsequent agreement period either directly by reducing the historical spending that forms the basis for its rebased benchmark or indirectly by reducing regional expenditures in the ACO's regional service area leading to negative (or smaller positive) regional adjustments. Under the proposal to incorporate an adjustment for prior savings, ACOs that have demonstrated prior savings would receive higher benchmarks under the following scenarios:

- ACOs with a negative regional adjustment would receive either a smaller negative regional adjustment or a positive adjustment for prior savings, depending on the relative size of the negative regional adjustment and their pro-rated average prior savings.

• ACOs with a positive regional adjustment whose pro-rated average prior savings multiplied by 50 percent are higher than their regional adjustment would receive a prior savings adjustment that is larger than their regional adjustment would have been under current policy. In contrast, ACOs whose positive regional adjustment is greater than 50 percent of their pro-rated average prior savings would not be impacted by the proposed adjustment for prior savings, and would continue to receive the (larger) regional adjustment.

We believe the proposed methodology to take the greater of the regional adjustment and the adjustment for prior savings when the regional adjustment is positive, and to net out a negative regional adjustment with the prior savings adjustment when the regional adjustment is negative, would prevent the proposed policy from resulting in unduly large benchmarks. While no ACOs would receive a lower benchmark as a result of this policy, numerical modeling of the proposed policy using PY 2020 data suggests that approximately 22 percent of all ACOs would receive a higher benchmark under this policy. Among ACOs that would receive a higher benchmark, the average net effect on per capita benchmark expenditures would be approximately $130 measured across each of the four enrollment types.

When the historical benchmark is adjusted for changes in severity and case mix between BY3 and the performance year as proposed under § 425.652(a)(10) and updated for growth in expenditures between BY3 and the performance year as proposed under § 425.652(b), the portion of the historical benchmark attributable to the prior savings adjustment would also be updated for changes in severity and case mix and growth in expenditures at the enrollment type level. This is consistent with the way in which the regional adjustment that is currently calculated under § 425.601(a)(8) (and would be calculated under propose § 425.656), is updated at the time of financial reconciliation to reflect changes in severity and case mix and growth in expenditures. If the portion of the benchmark attributable to prior savings were not updated for changes in severity and case mix and growth in expenditures, this could result in smaller benchmarks if the updates for severity and case mix and growth in expenditures are positive (which is typical in past experience). Thus, including the prior savings adjustment in these updates would tend to result in larger benchmarks for those ACOs that receive a prior savings adjustment to their benchmark. We believe that this is appropriate because the prior savings adjustment is based on reductions in expenditures in previous performance years. To the extent that updates to the benchmark for changes in severity and case mix and growth in expenditures suggest that the benchmark should be increased, we believe that it is appropriate to increase the size of the prior savings adjustment proportionally. Similarly, in the less likely scenario that updates for severity and case mix and growth in expenditures are negative, we believe it is appropriate to commensurately decrease the size of the prior savings adjustment.

We propose that the methodology for calculating the average per capita prior savings amount, including the use of a proration factor to account for any upward growth in the ACO's assigned population in the benchmark years of the current agreement as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period(s), would be specified in a new provision at § 425.658 applicable for agreement periods beginning on January 1, 2024, and in subsequent years. This new section would also specify the approach to determining an ACO's eligibility for the prior savings adjustment. Further, we propose to specify in § 425.652(a)(8) the approach for comparing the pro-rated average prior savings amount calculated under § 425.658 with the ACO's regional adjustment amount described in the new provision at § 425.656(c), to determine the applicability of the prior savings adjustment, the regional adjustment, or a combination of these two adjustments. We also propose to specify at § 425.652(a)(9) that for the second and each subsequent performance year during the term of the ACO's agreement period, we would redetermine the proration factor used in calculating the prior savings adjustment under § 425.658 to account for any changes in the ACO's assigned beneficiary population in the benchmark years due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology. Refer to section III.G.5.i. of this proposed rule for a discussion of the organization of the proposed new provisions in 42 CFR part 425, subpart G.

We seek comment on this proposal to adjust the ACO's historical benchmark for savings generated in the ACO's prior agreement period.

(5) Reducing the Impact of the Negative Regional Adjustment

(a) Background

In earlier rulemaking we have discussed our use of the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area (81 FR 37962). As described elsewhere within this section of this proposed rule (section III.G.5.c.(1)), CMS initially established a regional adjustment in a benchmark rebasing methodology that applied to ACOs entering a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019 (§ 425.603(c) through (g)), prior to applying this adjustment program wide beginning with agreement periods starting on July 1, 2019, and in subsequent years (§ 425.601(a)(8)).

In accordance with § 425.601(a)(8), for ACOs in agreement periods beginning on or after July 1, 2019, we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark (referred to herein as the ''regional adjustment''). The percentage that is applied in calculating the regional adjustment is determined in accordance with § 425.601(f) and depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of the applicable weights. For an ACO that has lower spending compared to its regional service area, the weight applied to the regional adjustment is 35 percent for the first agreement period in which the ACO is subject to a regional adjustment and 50 percent in the ACO's second and subsequent agreement periods subject to a regional adjustment. For an ACO that has higher spending compared to its regional service area, the weight is 15 percent for the first agreement period in which the ACO is

subject to a regional adjustment, increasing to 25 percent, 35 percent, and 50 percent, for the second, third, and fourth and subsequent agreement periods that an ACO is subject to a regional adjustment, respectively.

We cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (referred to herein as positive or negative 5 percent of national per capita FFS expenditures for assignable beneficiaries, and as the ''symmetrical cap;'' terms which we consider to be synonymous).

Table 59 illustrates how the regional adjustment is calculated under the current policy. For this hypothetical ACO, assumed to be in its first agreement period subject to a regional adjustment, the ACO has lower spending than its regional service area for the ESRD and aged/dual eligible populations (that is, the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures is positive) and higher spending for its disabled and aged/non-dual eligible populations (that is, the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures is negative). The weighted average difference between the region and the ACO, which is used to calculate the ACO's regional adjustment, is determined first by multiplying the difference between average per capita FFS expenditures for the ACO's regional service area and the ACO's average per capita historical benchmark expenditures for each Medicare enrollment type by its respective enrollment type proportion and then summing across the four enrollment types. In this example, because the weighted average is negative (−$495), the ACO is considered to have higher (overall) spending than its regional service area. Thus, the weight used to calculate the regional adjustment for this ACO based on the schedule of weights described in § 425.601(f) is 15 percent. This regional adjustment percentage weight is applied to the difference between the ACO's average per capita regional expenditures and the ACO's average per capita historical benchmark expenditures for each enrollment type (whether positive or negative) to obtain the uncapped regional adjustment for each enrollment type. When comparing these uncapped values to the symmetrical cap of 5 percent of national per capita FFS expenditures for assignable beneficiaries, only the ACO's positive ESRD adjustment is constrained by the cap. The ultimate impact of the symmetrical cap is to increase the ACO's overall weighted average regional adjustment from −$74 to −$77.

TABLE 59: Hypothetical Example of Regional Adjustment Calculation under Current Policy

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Difference Between Average Per Capita Expenditures for ACO's Region and ACO's Historical Benchmark ($)	Weight	Uncapped Regional Adjustment ($)	5% of National Assignable Per Capita Expenditures ($)*	Capped Regional Adjustment ($)
ESRD	0.020	29,667	15%	4,450	4,299	4,299
Disabled	0.170	-1,120	15%	-168	591	-168
Aged/dual	0.110	2,827	15%	424	880	424
Aged/non-dual	0.700	-1,727	15%	-259	528	-259
Weighted Average		-495		-74		-77

*Values in column "5% of National Assignable Per Capita Expenditures ($)" reflect values from the performance year from July 1, 2019, through December 31, 2019 (referred to as 2019A).

As discussed in the ''Regulatory Background'' (section III.G.5.c.(1) of this proposed rule), the current schedule of weights described in § 425.601(f)) and the positive or negative 5 percent cap on the regional adjustment described in § 425.601(a)(8)(ii)(C)) were finalized in the December 2018 final rule (83 FR 68017 through 68024). These policies were designed to address a dynamic where the regional adjustment could provide overly inflated benchmarks for ACOs that are relatively low spending compared to their region, while ACOs with higher spending compared to their region may find little value in remaining in the program when faced with a significantly reduced benchmark. We also explained our belief that these policies would make the benchmark more achievable for ACOs that care for medically complex patients and are high spending compared to their region, thereby encouraging their continued participation, while at the same time preventing windfall shared savings payments for ACOs that have relatively low spending levels relative to their region (83 FR 67822).

As discussed in the section entitled ''Overview of Considerations for Modification to the Benchmarking Methodology'' (section III.G.5.c.(2) of this proposed rule), we now believe that the existing negative 5 percent cap may not limit the negative regional adjustment enough to provide sufficient incentive for participation among ACOs serving high cost, medically complex populations. We are concerned that setting the cap on negative regional adjustments at negative 5 percent may limit opportunities for these beneficiaries, who arguably have the greatest need, to receive coordinated care, as well as potential savings for the Trust Funds. Therefore, we believe it is important to further reduce the impact of negative regional adjustments, particularly for ACOs caring for high cost populations, including high-risk patients and beneficiaries dually eligible for Medicare and Medicaid, beyond what is allowed under the current regulation at § 425.601(a)(8)(ii)(C).

(b) Proposed Revisions

We propose to institute two policy changes designed to limit the impact of

negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries:

- Reduce the cap on negative regional adjustments from negative 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries to negative 1.5 percent.
- After the cap is applied to the regional adjustment, gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted-average prospective HCC risk score increases.

The choice of a negative 1.5 percent cap is informed by CMS' experience with use of a 2 percent cap on negative regional expenditure adjustments under the Global and Professional Direct Contracting Model (to be redesigned and renamed as the ACO Realizing Equity, Access, and Community Health (REACH) Model beginning January 1, 2023), as well as considerations related to the potential longer-term vision for use of an administratively set benchmark under which a negative discount for less efficient ACOs could be approximately 1.6 percent over the ACO's agreement period as described in our comment solicitation on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program (section III.G.7. of this proposed rule).

Under this proposal, we would continue to apply a cap equal to positive 5 percent of national per capita expenditures for assignable beneficiaries to positive regional adjustments for each enrollment type. Table 60 illustrates how the cap would be applied asymmetrically to positive and negative regional adjustments under this proposal.

TABLE 60: Hypothetical Example of Proposed Cap on Regional Adjustment

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Uncapped Regional Adjustment ($)	5% of National Assignable Per Capita Expenditures ($)	-1.5% of National Assignable Per Capita Expenditures ($)	Capped Regional Adjustment ($)
ESRD	0.020	4,450	4,299	-1,290	4,299
Disabled	0.170	-168	591	-177	-168
Aged/dual	0.110	424	880	-264	424
Aged/non-dual	0.700	-259	528	-158	-158
Weighted Average		-74			-7

The hypothetical ACO in this example had a mix of positive and negative regional adjustments across the four enrollment types. The ACO's uncapped ESRD adjustment is positive and above the positive 5 percent cap. Therefore, it falls from $4,450 to $4,299 when the cap is applied. The ACO's uncapped aged/non-dual eligible adjustment is outside the new negative 1.5 percent cap and thus falls from −$259 to −$158 when the cap is applied. The ACO's disabled and aged/dual eligible adjustments are both under the applicable caps and are unaffected. The ACO's overall weighted average regional adjustment (calculated by multiplying the adjustment for each enrollment type by the corresponding enrollment type proportion and then summing across the four enrollment types) falls from −$74 to −$7 when the cap is applied. Note that under the current policy with a symmetrical cap equal to 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries, only the ACO's ESRD adjustment would be constrained. The ACO's aged/non-dual eligible adjustment would remain at −$259 and the ACO's overall adjustment would actually become more negative (−$77) after capping (as shown in Table 59).

For negative regional adjustments, we also propose to apply an offset factor based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries)[260] and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types. Before taking this weighted average, the risk score for each enrollment type would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Specifically, the offset factor would be calculated as:

Offset factor = [A] + ([B] − 1)

This offset factor would be applied to negative regional adjustments after the negative 1.5 percent cap is applied. The offset factor would be subject to a minimum of zero and a maximum of one. We would apply the offset factor by subtracting its value from 1 and multiplying this difference by the negative regional adjustment for each Medicare enrollment type, calculated as:

Final regional adjustment = Negative regional adjustment × (1 − Offset factor)

The higher an ACO's proportion of dual eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment (that is, the negative weighted average regional adjustment would be fully offset). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

To illustrate how the offset would be calculated and applied, assume that the hypothetical ACO from Table 60 had a proportion of dual eligible beneficiaries of 0.220 and a weighted average prospective HCC risk score for BY3 of

[260] In computing this proportion, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually elibible for Medicare and Medicaid.

1.389. The offset factor for this ACO would be calculated as:

Offset factor = 0.220 + (1.389 − 1) = 0.609

This factor would be applied as illustrated in Table 61 by multiplying the negative regional adjustment for each applicable Medicare enrollment type by 1 minus the offset factor or 0.391.

TABLE 61: Hypothetical Example of Proposed Offset Factor Applied to Negative Regional Adjustments

Medicare Enrollment Type	Enrollment Proportion	Capped Regional Adjustment (Before Offset) ($)	Offset Factor	1 – Offset Factor	Final Regional Adjustment ($)
ESRD	0.020	4,299	N/A	N/A	4,299
Disabled	0.170	-168	0.609	0.391	-66
Aged/dual	0.110	424	N/A	N/A	424
Aged/non-dual	0.700	-158	0.609	0.391	-62
Weighted Average		-7			78

Here, the offset factor would be applied to the regional adjustments for the disabled and aged/non-dual eligible populations, as both are negative, but not to the regional adjustments for the ESRD and aged/dual eligible populations, which are both positive. Taking the weighted average across the enrollment types following application of the offset factor shows that the ACO's overall weighted regional adjustment goes from −$7 before the offset to $78 after the offset, a positive per capita impact of $85.

We note that it is possible for an ACO to benefit from one aspect of this proposed policy, but not the other. For example, ACOs that have negative regional adjustments that are below the negative 1.5 percent cap will not be affected by the proposed reduction to the cap but could still benefit from the proposed offset factor. Alternatively, an ACO whose negative adjustment is reduced by the negative 1.5 percent cap would receive no further benefit from the offset factor if it has a low proportion of dual eligible beneficiaries or a low risk score such that the offset factor equals 1.

We simulated the combined impact of these policy proposals using data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019. The results of this simulation are summarized in Table 62.

TABLE 62: Simulated Impact of Proposed Negative 1.5% Cap and Offset Factor to Negative Regional Adjustments

	Total ACOs	ACOs with Negative Weighted Average Regional Adjustment Under Current Policy	ACOs with Positive Weighted Average Regional Adjustment Under Current Policy
Number of ACOs			
Total	356	43	313
No Impact	146	3	143
Impacted	210	40	170
Impacted by -1.5% Cap Only	8	0	8
Impacted by Offset Factor Only	117	26	91
Impacted by Both	85	14	71
Per Capita Impact among Impacted ACOs			
Average	$25.66	$113.92	$4.89
Minimum	< $0.01	$0.57	< $0.01
Maximum	$789.22	$789.22	$72.40

Under these policy proposals, the negative regional adjustment for almost every ACO that had a negative regional adjustment under current policy (40 out of 43 ACOs) would have been reduced (or eliminated), with an average per capita impact of approximately $114. ACOs with higher weighted-average BY3 prospective HCC risk scores and higher proportions of dual eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. Four ACOs in the simulation had an offset factor of 1, meaning they received a full offset to their negative regional adjustments. An additional 170 ACOs that had a positive weighted average regional adjustment under the current policy but that had at least one enrollment type with a negative regional

adjustment would also have benefitted from the combined policy. The average per capita impact among these ACOs was smaller at around $5. We believe that the impacts observed in our simulation are likely to grow larger as more ACOs progress further in the program and are subject to higher weights in the calculation of the regional adjustment, and as more ACOs that serve high cost and medically complex populations join the program.

We considered whether to make the proposed changes applicable only to ACOs that would have had a negative weighted average regional adjustment under the current policy (that is, ACOs for which the regional adjustment has an overall negative impact on the per capita historical benchmark). However, we believe that applying the lower cap and the offset factor at the enrollment type level is more straightforward and will have the opportunity to benefit ACOs that may be serving high risk populations in at least one, but not all Medicare enrollment types.

We seek comment on these proposed changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years. These proposed changes would be reflected in the proposed new regulation at § 425.656. We also propose to specify in paragraph (a)(8) of the proposed new regulation at § 425.652, also applicable for agreement periods beginning on January 1, 2024, and in subsequent years, the approach for comparing the pro-rated average prior savings amount (described in the proposed new provision at § 425.658(b)(3)(ii), and as discussed in section III.G.5.c.(4) of this proposed rule) with the ACO's regional adjustment amount (described in the proposed new provision at § 425.656(c)), to determine the applicability of a prior savings adjustment, the regional adjustment, or a combination of these two adjustments.

(6) Alternative Options for Addressing Concerns About the Effect of an ACO's Assigned Beneficiaries on Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

ACOs and other interested parties have expressed concerns with CMS' approach to determining regional FFS expenditures using a population of assignable beneficiaries that includes the ACO's assigned beneficiaries including, with respect to the impact on the calculation of the regional adjustment and the blended national-regional growth rate used to trend and update an ACO's historical benchmark, suggesting this policy results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which may tend to be ACOs located in rural areas. In the CY 2022 PFS proposed rule (86 FR 39291 through 39294), we sought comment on a number of potential approaches to addressing these concerns, as well as any unintended consequences that may result from removing an ACO's assigned beneficiaries from regional calculations. We summarized comments received in the CY 2022 PFS final rule (86 FR 65296 through 65302). In sections III.G.5.c.(3) through (5) of this proposed rule, we are proposing a package of three proposals: incorporating a prospective, external factor in the growth rates used in updating the benchmark; adjusting rebased benchmarks to account for an ACO's prior savings; and reducing the impact of negative regional adjustments on ACO benchmarks. We believe this package of proposals would, among other things, address concerns associated with including an ACO's own beneficiaries on its regional FFS expenditures. For example, the proposed inclusion of the ACPT in the growth rates used to update the benchmark based on a three-way blend would reduce the impact of including an ACO's assigned beneficiaries in the regional component of the blend. Under the proposal to use the higher of the prior savings adjustment or positive regional adjustment, the proposed prior savings adjustment could increase the historical benchmark for an ACO whose regional adjustment could have been decreased by the inclusion of its own assigned beneficiaries in the regional expenditure calculation.

We considered alternative options to this package of three proposals described in sections III.G.5.c.(3) through (5) of this proposed rule, that would more directly reduce the effect of the ACO's own beneficiaries on its regional FFS expenditures: (1) removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations; and (2) expanding the definition of the ACO's regional service area to use a larger geographic area to determine regional FFS expenditures. We note that these related approaches were among the policies we discussed and on which we sought comment in the CY 2022 PFS proposed rule. We also considered whether to use a combination of these two alternative approaches under which we would expand the ACO's regional service area in combination with removing an ACO's assigned beneficiaries from the assignable beneficiary population used in calculating regional FFS expenditures. In evaluating these alternative approaches, we considered the comments we received in response to that comment solicitation (summarized in the CY 2022 PFS final rule) and considered the extent to which each alternative would address three core concerns (or dynamics) previously described in section III.G.5.c.(2) of this proposed rule and summarized here:

- Mitigating the ratchet effect to ensure ACOs' rebased benchmarks remain accurate and serve as a reasonable baseline.
- Reducing a single ACO's or multiple ACOs' collective impacts on an ACO's regional expenditures, which are used to calculate the regional adjustment and the regional portion of the trend and update factors.
- Ensuring the benchmarking methodology results in benchmarks of sufficient value to encourage program entry and continued participation by ACOs, ACO participants, and ACO providers/suppliers serving medically-complex, high-cost populations.

We also considered the extent to which the alternatives could lead to other unintended consequences including introducing excessive benchmark volatility or creating incentives for market consolidation. We note some of these alternatives may require use of our authority under section 1899(i)(3) of the Act to implement alternative benchmarking methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, including alternative approaches to updating the historical benchmark. In order to use our authority under section 1899(i)(3) of the Act, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. As of the time of this proposed rule, we have not performed an analysis of the extent to which the alternative approaches described in this section of this proposed rule would meet the requirements of section 1899(i)(3) of the Act, when use of this authority would be necessary for implementing such approaches within the Shared Savings Program's financial methodology.

In the remainder of this section, we describe in more detail the alternative options that we considered, as well as our assessment of the ability of each alternative to address the three core concerns we articulated and other factors considered earlier in this section.

We are again seeking comment on these alternative options with interested parties now having the opportunity to consider their merits relative to the package of policies we are proposing in sections III.G.5.c.(3) through (5) of this proposed rule. We are also seeking comment on certain operational factors that we would need to address with greater specificity if we were to finalize any of the alternatives. We will consider the comments received on these alternative options along with the comments on the proposed package of policies in the development of our final policy, and may consider adopting one or both of the alternatives discussed in this section in lieu of the package of policies we are proposing in section III.G.5.c.(3) through (5) of this proposed rule.

Alternative 1: Removing an ACO's Assigned Beneficiaries From the Assignable Beneficiary Population Used in Regional Expenditure Calculations

Under the first alternative considered, which aligns with suggestions made by some ACOs and other interested parties, we would exclude an ACO's assigned beneficiaries from the population of assignable beneficiaries in the ACO's regional service area used to determine the regional FFS expenditures used in all benchmarking calculations including trending and updating the benchmark and calculating the regional adjustment. If we were to adopt this first alternative to remove the ACO's own assigned beneficiaries but not also adopt the alternative to expand the ACO's regional service area under a combined approach, the ACO's regional service area would remain as all counties where one or more beneficiaries assigned to the ACO reside (as defined under § 425.20). If we were to adopt a combined alternative, we would consider a modified definition of the ACO's regional service area. To remove an ACO's assigned beneficiaries from the regional expenditure calculation, we would use the mathematical approach described in the CY 2022 PFS proposed rule (86 FR 39292 and 39293), which relies on the premise that per capita risk adjusted FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share [261] and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) × (ACO's regional market share)] + [(c) × (1 − ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, we would insert the applicable values for (a), (b), and regional market share (all data elements already computed under the current benchmarking methodology) into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) − [(b) × (ACO's regional market share)]}/(1 − ACO's regional market share).

By using such ACO- and regional-level values, this approach, performed separately by Medicare enrollment type, would avoid the need to calculate individualized ACO county-level risk-adjusted expenditures. As such, and by leveraging existing data elements, we believe this approach would pose relatively limited operational burden.

As described in the CY 2022 PFS final rule, some of the commenters responding to our initial comment solicitation indicated CMS' mathematical approach was ''directionally correct,'' relatively simple, and would work well in nearly every case while using data that CMS already produces (86 FR 65299 and 65300). However, we share the concerns raised by several commenters that an approach to remove an ACO's assigned beneficiaries from the assignable population could incentivize ACOs to ''cherry-pick'' healthier, lower-cost patients and could unfairly penalize ACOs that specialize in more medically-complex, higher-cost patients, running counter to one of the core dynamics we seek to address (86 FR 65300 and 65301). Similarly, we are also concerned that this approach would incentivize market consolidation, as ACOs may anticipate a benefit to maintaining the largest market share in the region if their own assigned beneficiaries are removed from the assignable population. Additionally, removing an ACO's assigned beneficiaries from the calculation of regional FFS expenditures could yield unstable estimates due to small sample sizes in areas with high program penetration and/or in rural areas. As a result, an approach that would remove an ACO's assigned beneficiaries from the assignable population used to calculate regional FFS expenditures could result in a situation where the ACO's assigned population is relatively healthier and less costly than the assignable beneficiary population in the regional service area, which in turn would result in higher benchmarks for ACOs and thereby greater shared savings payments and reduced shared losses. More generous benchmark updates resulting from this approach could jeopardize CMS' use of the statutory authority under section 1899(i)(3) of the Act to adopt such an alternative approach. We believe these concerns are relevant to whether we adopt this alternative alone or adopt a combined approach, under which we would both remove the ACO's own assigned beneficiaries from the regional expenditure calculation and expand the ACO's regional service area for purposes of that calculation. Expanding the regional service area may also mitigate the concern about unstable estimates due to small sample sizes.

While we believe that this first alternative would partially address one of our core concerns summarized at the start of this section by removing an ACO's own impact on the regional expenditures used in its benchmark calculations, it would not directly address the collective impact of multiple ACOs that may be operating in the same regional service area. Under the proposed changes designed to increase participation in the Shared Savings Program, discussed elsewhere within this proposed rule, we would expect this issue to grow more prominent over the coming years.[262] Additionally, we believe that removing an ACO's own assigned beneficiaries from the regional expenditure calculation would be less effective at mitigating the ratchet effect than our proposed package of policies. For example, while this alternative might address how the ACO's prior performance affects regional factors used for purposes of calculating an ACO's rebased historical benchmark, this alternative would not address the concern that actual assigned beneficiary expenditures used in establishing an ACO's rebased historical benchmark may already be reduced by the ACO's prior success in reducing expenditures for its own assigned beneficiary population. The proposed adjustment

[261] What is referred to here as the ''ACO's regional market share'' is the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO, which is the weight that it is applied to the national component of the national-regional blend under § 425.601(a)(5)(iv) and (v).

[262] CMS has set forth a goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.

for prior savings described in section III.G.5.c.(4) of this proposed rule would more directly address this concern by adding a portion of the ACO's prior savings during the benchmark years back into the rebased benchmark. Further, our proposal to include the ACPT in a three-way blended update factor as described in section III.G.5.c.(4) of this proposed rule would more directly ''decouple'' the update factor from actual observed expenditures, including expenditure reductions that are a result of savings already achieved by the ACO, than simply removing the ACO's own beneficiaries from the regional expenditure calculation.

One option that has been suggested by commenters is to remove all Shared Savings Program assigned beneficiaries from the assignable beneficiary population used to calculate each ACO's regional expenditures. After careful consideration, at this time we decline to consider removing all Shared Savings Program assigned beneficiaries from the assignable beneficiary population used to calculate each ACO's regional expenditures, as we have concerns about the short- and long-term sustainability and soundness of such an approach given the Agency's goal to expand participation in accountable care. We believe that under the current level of program participation, an approach that would remove all Shared Savings Program assigned beneficiaries from the assignable population for each ACO's regional service area would yield unstable estimates of regional FFS expenditures for some ACOs, even if we were to expand the definition of an ACO's regional service area. Over time, we would expect this issue to worsen as Shared Savings Program participation expands.

If we were to seek to finalize the first alternative of removing an ACO's assigned beneficiaries from the calculation of regional expenditures either by itself or in the combination with expanding our definition of an ACO's regional service area in lieu of our proposed package of policies, we anticipate that we would potentially need to adjust the weights currently used in calculating the regional adjustment to the historical benchmark. Under the current regulations, for ACOs that have lower average spending than their regional service area, we use a weight of 35 percent in the first agreement period that an ACO is subject to a regional adjustment and a weight of 50 percent in the second and subsequent agreement periods the ACO is subject to a regional adjustment. If an ACO was serving an assigned population that is markedly healthier than other assignable beneficiaries in the ACO's regional service area, removing the ACO's assigned beneficiaries from the population used to compute regional expenditures would increase the magnitude of the regional adjustment, all else being equal. This could potentially lead to a dramatic increase in program costs as higher regional adjustments could translate to higher shared savings payments. Thus, we would potentially need to consider reducing the weights used to calculate the regional adjustment to protect the Medicare Trust Funds. Determining the appropriate adjustment to the weights may be complicated by potential resulting consolidation. For example, assume for illustration purposes that the regional adjustment weights were reduced by 10 percentage points to bring the overall impact of regional adjustments back in line with the existing program design (that is, the weighting would be reduced from 35 to 25 percent in the first agreement period if positive, 50 percent to 40 percent in succeeding agreement periods if positive, etc.). If ACOs consolidate in order to concentrate the residual regional spending on fewer higher spending assignable beneficiaries, then the weights may need to be further reduced to offset the further increase in regional adjustments for consolidated ACOs.

Alternative 2: Expanding the Regional Service Area

The second alternative we considered in place of the package of policies that we are proposing would seek to reduce an ACO's influence on expenditures in its regional service area by expanding the ACO's regional service area. While we did not outline a specific approach in the CY 2022 PFS proposed rule (86 FR 39294), we sought comment on basing regional expenditure calculations on larger geographic areas, such as using State-level data or Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/State expenditures). We also sought comment on what would constitute heavy market penetration by an ACO in its regional service area if we were to use an approach that would consider the ACO's level of penetration in determining whether to expand the ACO's regional service area.

For example, one potential approach to expanding the regional service area would be to define an ACO's regional service area to include all States in which at least one of the ACO's assigned beneficiaries resides and calculating regional expenditures as a weighted average of State-level risk adjusted expenditures, with the weights reflecting the proportion of the ACO's total assigned beneficiaries residing in each State. This approach would therefore mimic the current calculation, but replace county-level data with State-level data.

Another possible approach would be to follow the existing methodology, but replace county-level risk adjusted expenditure values with State-level risk adjusted expenditure values for the corresponding State only for counties where an ACO has market share above a specified threshold, such as 50 percent. Such a blended approach would maintain greater geographic specificity than an approach that relies exclusively on State-level data, while still reducing the influence of an ACO's own beneficiaries in areas where the impacts may be most acute.

In its comment responding to our solicitation, MedPAC favored altering the calculation of regional spending by extending the ACO's regional service area to a larger market area (for example, CBSAs, health service areas, or hospital referral regions) in lieu of removing ACO assigned beneficiaries from the calculation of regional FFS expenditures, noting that expanding an ACO's regional service area would help to reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain categories of ACOs (for example, historically low spending ACOs). Other commenters also supported expanding the regional service area for the purposes of calculating regional FFS expenditures in cases where ACO market penetration is high, with some of those commenters suggesting this would mitigate concerns about the reference population being too small after removing the ACO's assigned beneficiaries. Some commenters specifically called for using a threshold of 50 percent market penetration in such an approach. For example, a commenter suggested expanding the regional service area to include all contiguous counties for ACOs that have high market penetration (for example, when an ACO's assigned beneficiary population in a county exceeds 50 percent), with allowances for a lower threshold under special circumstances. For a full summary of the considerations and comments received, refer to the CY 2022 PFS final rule (86 FR 65301 and 65302).

Like MedPAC, we believe that adopting only this second alternative to expand the regional service area would reduce the impact of an ACO's own expenditures on its regional

expenditures without introducing incentives for favorable patient selection or concerns about increased volatility that may result from the first alternative of excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures. However, like that first alternative, expanding the regional service area might not address concerns about ACOs' collective market penetration. We also believe that this second alternative or a combined approach would do less to ''decouple'' the ACO's benchmark from observed FFS spending than the package of policies that we are proposing, and thus would likely be more limited in countering the ratchet effect. By contrast, our proposal to incorporate the ACPT into the growth rates used to update the benchmark would ensure that a portion of the update will remain unaffected by observed FFS spending. Furthermore, we have concerns that use of a market penetration threshold may drive further market consolidation as ACOs seek to meet such a threshold.

If we were to decide to finalize this second alternative or a combined approach in lieu of our proposed package of policies, there are a number of operational factors that we would need to address with greater specificity, including, but not limited to: what alternative geographic area we would use, whether we would replace county-level data with data based on an alternate geographic area or use a blend, and, if using a blend, at what threshold it would be triggered, and what weights would be applied when aggregating expenditures across geographic areas.

On the balance, we believe that our proposed package of policies described in sections III.G.5.c.(3) through (5) of this proposed rule would collectively be more effective at addressing the core concerns we articulated than the two alternatives described or a combined approach, and would avoid some of the alternatives' potential unintended consequences. However, we seek further comment on these alternatives, including various operational considerations we would need to specify if we were to finalize either alternative 1, alternative 2, or a combined approach. As stated previously, we will consider the comments received on these alternative options and the related operational considerations along with the comments on the proposed package of policies in the development of our final policy, and may consider adopting one or both of the alternatives discussed in this section in lieu of the package of policies we are proposing in section III.G.5.c.(3) through (5) of this proposed rule.

d. Calculating County FFS Expenditures To Reflect Differences in Prospective Assignment and Preliminary Prospective Assignment With Retrospective Reconciliation

(1) Background

Under the current regulation at § 425.601, CMS uses risk adjusted county-level FFS expenditures, determined based on expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to the relevant benchmark or performance year, to calculate factors used in establishing, adjusting and updating the ACO's historical benchmark. Specifically, we use these risk adjusted county-level FFS expenditures to determine the ACO's regional service area expenditures, which are used to calculate the regional adjustment in accordance with § 425.601(a)(8) and the blended national-regional growth rates used to trend forward expenditures for BY1 and BY2 to BY3 dollars (§ 425.601(a)(5)), and to update the ACO's historical benchmark between BY3 and each performance year in the ACO's agreement period (§ 425.601(b)).

To calculate the risk adjusted regional expenditure amounts under § 425.601(d) for each Medicare enrollment type, we first calculate risk adjusted expenditures for the relevant benchmark year or performance year for assignable beneficiaries in each county in the ACO's regional service area in accordance with § 425.601(c). We then weight these county-level risk adjusted expenditure amounts by the proportion of the ACO's assigned beneficiaries residing in each county, and sum across all counties in the ACO's regional service area. Additionally, we use county-level assignable beneficiary person years in combination with the ACO's assigned beneficiary person years by county to calculate an ACO's share of assignable beneficiaries in the ACO's regional service area as described in § 425.601(a)(5)(v). These shares are, in turn, used to determine the weights used in calculating the blended national-regional trend and update factors as described in §§ 425.601(a)(5)(iv) and (v) and 425.601(b)(4).

The assignable population of beneficiaries used to calculate the county level values described above is identified in accordance with the definition of ''assignable beneficiary'' under § 425.20. Specifically, an assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). When first proposing to incorporate regional and national factors based on the assignable beneficiary population in the February 2016 proposed rule (81 FR 5843 through 5845), we discussed our consideration of which assignment window to use to identify the assignable population used to calculate inputs to the program's financial calculations. Specifically, we considered using the 12-month period based on a calendar year which aligned with the assignment window for preliminary prospective assignment with retrospective reconciliation, or an offset 12-month period which aligned with the assignment window for prospective assignment (for example, October through September preceding the calendar year). We proposed, and ultimately finalized, use of the 12-month period based on the calendar year for all ACOs, regardless of the ACO's assignment methodology (81 FR 37985 through 37989).

In the February 2016 proposed rule (81 FR 5843 and 5844), and as restated in the June 2016 final rule (81 FR 37985 and 37986), we expressed our belief that it is important to calculate regional and national FFS factors consistently program-wide, so as not to advantage or disadvantage an organization simply on the basis of the assignment methodology that applied under its track. We also noted our belief that this consistency would help to ensure a level playing field in markets where multiple ACOs are present and would also simplify program operations. We indicated that we would monitor for observable differences in the health status (for example, as identified by prospective HCC risk scores) and expenditures of the assignable beneficiaries identified using the 12-month calendar year assignment window, as compared to assignable beneficiaries identified using the offset assignment window (for example, October through September preceding the calendar year) and would, if warranted, address the need for additional adjustments to account for the use of assignable beneficiaries identified using an assignment window that is different from the assignment window used to assign beneficiaries to the ACO through future rulemaking.

In addition to these inputs based on county-level assignable beneficiary data, the Shared Savings Program's financial calculations also use the assignable

beneficiary population to calculate a variety of factors based on national FFS expenditures, including:

- National growth rates used to trend and update the benchmark (see § 425.601(a)(5)(ii) and § 425.601(b)(2));
- Thresholds used to truncate beneficiary expenditures (see §§ 425.601(a)(4), 425.601(c)(3), 425.605(a)(3) and 425.610(a)(4)(ii));
- Caps applied to the regional adjustment (see § 425.601(a)(8)(ii)(c)); and

Mean risk scores used to renormalize ACO- and county-level risk scores (see discussion in 83 FR 68007 through 68013).

Having gained experience using factors based on the assignable beneficiary population since PY 2017, and based on our monitoring of differences in expenditure and risk scores among beneficiaries identified using an assignment window based on the calendar year versus an offset assignment window, we have concluded that there exists a systematic bias in the calculations using county-level expenditures that favors ACOs under prospective assignment. Based on historical data, we have observed that for a given calendar year, risk adjusted expenditures for populations identified based on the offset assignment window are systematically lower than risk adjusted expenditures for populations identified based on the calendar year assignment window, all else equal. In the calculation of the regional adjustment, the favorable bias arises for ACOs under prospective assignment because we are comparing risk adjusted expenditure levels between populations identified based on different assignment windows for BY3: the ACO's own assigned beneficiary population identified based on the offset assignment window, and expenditures for the assignable population of beneficiaries in the ACO's region identified based on the calendar year assignment window. This mismatch causes the ACO's spending to look ''low'' relative to the regional spending, leading to a larger positive (or smaller negative) regional adjustment than we would observe if the assignment windows used to identify the two populations were consistent.

Based on modeling using historical benchmarks for ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019, and after accounting for regional adjustment weighting and capping, we estimate that actual regionally adjusted historical benchmarks were 0.2 percent to 1.9 percent higher for ACOs under prospective assignment than they would have been if the regional adjustment had been calculated using risk adjusted regional expenditures for assignable beneficiaries identified using the offset assignment window used under prospective assignment. The median estimated bias was 1.0 percent. We believe the program-wide impact of this bias was likely low in the initial years that the regional adjustment was in effect because only a subset of ACOs were originally eligible for the regional adjustment (ACOs that renewed for a second agreement period starting in January 2017, January 2018, or January 2019), and a relatively small share of those ACOs were under prospective assignment (ACOs participating in Track 3 or the Track 1+ ACO Model). Starting with agreement periods beginning on July 1, 2019, all ACOs became eligible to receive a regional adjustment and to select their assignment methodology in accordance with §§ 425.226(a)(1) and 425.400(a)(4)(ii). With this latter change, the share of ACOs under prospective assignment grew considerably, from around 17 percent in PY 2019 to 38 percent in PY 2022. Because of this, we believe that the bias has a larger impact currently than in earlier years.

Additionally, while risk adjusted expenditure trends have generally been consistent for prospectively and retrospectively determined assignable populations, this stable relationship was disrupted in the PHE for COVID–19 when decreased utilization led to expenditures for prospectively determined populations falling more sharply in CY 2020 than for retrospectively determined populations (due to an increase in the number of beneficiaries that did not utilize any care after being prospectively assigned to an ACO). This appears to have generated an additional 1.0 percentage point increase in measured savings (relative to total benchmark) for ACOs under prospective assignment in PY 2020 beyond the effect of the biased regional adjustment. However, we note that between CY 2020 and CY 2021 expenditures grew more quickly for prospectively determined populations, causing cumulative trends from years preceding the PHE for COVID–19 to CY 2021 to return to a roughly parallel state for the two populations. Although the disruption of expenditure trends between prospective and retrospectively assignable populations was temporary in this case, the disruption of stable expenditure trends during the PHE for COVID–19 highlights the possibility of future biases in the blended national-regional growth factor. If the blended growth factor is based on an assignable population with a different expenditure growth trend than the expected trend in expenditures of an ACO's assigned population, an ACO could receive an artificial increase or decrease in savings.

Without correction, we believe that the impact of this bias has the potential to grow costlier to the Trust Funds over time. For one, more ACOs will be subject to higher weights used in calculating the regional adjustment as they progress in the Shared Savings Program, which is expected to lead to larger regional adjustments and, by extension, larger biases than those estimated in our analysis using benchmark data from the 6-month performance year beginning July 1, 2019, in which most ACOs were subject to the lowest regional adjustment weights. Second, as more ACOs move to the ENHANCED track with its 75 percent sharing rate, aggregate savings against a favorably biased benchmark will be shared by ACOs at a higher rate. Preventing further influence of the bias, as would be achieved under the proposed approach, is important for ensuring good stewardship of Medicare Trust Fund dollars. Addressing this bias in Shared Savings Program calculations for ACOs under prospective assignment would also ensure a more level playing field for ACOs under both assignment methodologies, and would improve the comparability of ACOs' performance under the Shared Savings Program irrespective of the ACO's chosen assignment methodology.

Further, if left unresolved, this bias would need to be taken into account as part of the regulatory impact analysis for evaluating proposed modifications to policies under the Shared Savings Program, and in considering whether CMS has met the requirements for use of other payment models under section 1899(i)(3) of the Act. The authority to use other payment models under section 1899(i)(3) of the Act is necessary for implementing key aspects of the Shared Savings Program, including the two-sided models and the blended national-regional growth factors used to update the historical benchmark (as discussed within section III.G.5.c.(3) of this proposed rule), as well as the proposal to provide AIPs to eligible ACOs (discussed within section III.G.2 of this proposed rule). This authority is contingent on the statutory requirement that other payment models adopted under section 1899(i)(3) of the Act must be determined to improve the quality and efficiency of items and services furnished to Medicare FFS beneficiaries and not to increase program spending relative to a baseline estimated for the

Shared Savings Program were it not to employ modifications authorized under section 1899(i)(3) of the Act. A predictable favorable bias would increase program spending (particularly in combination with modifications like two-sided risk sharing that require authority from section 1899(i)(3) of the Act), and therefore, jeopardize CMS' ability to satisfy the requirements of section 1899(i)(3) of the Act for use of other payment models.

We believe modification to the methodology for calculating regional FFS expenditures is necessary and timely to mitigate the observed favorable bias for ACOs under prospective assignment.

(2) Proposed Revisions

To remove the favorable bias and bring greater precision to the calculation of factors based on regional FFS expenditures, we are proposing to modify the calculation of risk adjusted regional expenditures used in the regional adjustment and in the regional component of the blended factors used to trend and update the benchmark (including, if finalized, the three-way blend proposed in section III.G.5.c.(3) of this proposed rule). Under this proposal, for agreement periods beginning on January 1, 2024, and in subsequent years, we would calculate risk adjusted regional expenditures using county-level values computed using an assignment window that is consistent with an ACO's assignment methodology selection for the performance year under § 425.400(a). That is, for ACOs selecting prospective assignment, we would use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we would continue to use an assignable population of beneficiaries that is identified based on the calendar year assignment window. We believe that removing the current mismatch in the assignment window used to determine the assignable population, and the assigned population for ACOs under prospective assignment would create a more equitable historical benchmark across assignment methodologies and help protect the Trust Funds. For consistency, we are also proposing to use an assignable population identified using an assignment window that corresponds to an ACO's selected assignment methodology to calculate other factors based on county-level data, namely, the weights used in computing the blended trend and update factors.

At this time, we are not proposing to change the way we would compute national factors that require identifying assignable populations. That is, all factors used in calculations that are based on the national assignable FFS population would continue to be computed using an assignable population identified based on the calendar year assignment window. This choice is driven by two factors. First, for simplicity, we favor using the same set of national values for all ACOs. Second, we do not believe the national factors, as currently computed, contribute to the current bias that we have observed and which is the motivation for the proposed policy changes. While using a national assignable population based on an offset assignment window to compute the national component of trend and update factors could help to further protect against unanticipated biases in those calculations, the national component represents a small portion of the blend for most ACOs. Thus, the additional protection provided would be limited. However, we intend to continue monitoring how national assignable expenditure trends hinge on the selection of assignment methodology, and may return to this issue in future rulemaking if significant biases exist that may systemically impact the national component of the trend and update factors.

We currently make available public use files (PUFs) containing the county level expenditures, risk scores and assignable beneficiary person years for each calendar year on the data.cms.gov website, specifically: (1) County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries PUF,[263] and (2) Number of ACO Assigned Beneficiaries by County PUF.[264] Interested parties are able to use these files to replicate the calculation of risk adjusted regional expenditures or the weights used in the blended trend and update factors. We also provide ACOs with program reports that include information on the geographic distribution of their assigned beneficiary populations which can also be used along with the county-level data based on the assignable population for modeling purposes.

If this proposal is finalized, we anticipate we would make two sets of county-level values publicly available for each calendar year: we would continue to provide county-level data on the assignable population identified based on the calendar year assignment window and would also make available county-level data based on the assignable population identified using the offset assignment window. Additionally, we would update the public use files that reflect the distribution of each ACO's assigned beneficiary population by county to include a field indicating each ACO's assignment methodology selection for the applicable performance year.

We believe additional data will facilitate modeling of the proposed changes to the calculation of county-level FFS expenditures used in Shared Savings Program benchmark calculations. Concurrent with the issuance of this proposed rule, we are making available through the Shared Savings Program website at *www.cms.gov/sharedsavingsprogram/* data files containing risk adjusted county-level FFS expenditures for 2018–2020 calculated based on an assignable beneficiary population identified using an offset assignment window.

The changes we are proposing would be specified in the proposed new regulations at §§ 425.652, 425.654, and 425.656. Refer to section III.G.5.i. of this proposed rule for a discussion of the organization of the proposed new provisions in 42 CFR part 425, subpart G.

We note that in order to finalize the proposed changes to the regional component of the update factor we would need to use our statutory authority under section 1899(i)(3) of the Act. We refer readers to section III.G.5.c.(3) and the Regulatory Impacts Analysis (section VII.) of this proposed rule for related discussions around the use of this authority with respect to the proposed modifications to the update factor.

We seek comment on these proposals.

e. Improving the Risk Adjustment Methodology to Better Account for Medically Complex, High Cost Beneficiaries and Guard Against Coding Initiatives

(1) Background

Currently, for ACOs in agreement periods beginning on or after July 1, 2019, we account for changes in severity and case mix of the ACO's assigned

[263] Refer to *Data.CMS.gov*, County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries, available at *https://data.cms.gov/medicare-shared-savings-program/county-level-aggregate-expenditure-and-risk-score-data-on-assignable-beneficiaries.*

[264] Refer to *Data.CMS.gov*, Number of Accountable Care Organization Assigned Beneficiaries by County, available at *https://data.cms.gov/medicare-shared-savings-program/number-of-accountable-care-organization-assigned-beneficiaries-by-county.*

beneficiary population when establishing the benchmark for an agreement period and also in adjusting the benchmark for each performance year during the agreement period. In accordance with § 425.601(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using CMS Hierarchical Condition Category (CMS–HCC) prospective risk scores (herein referred to as prospective HCC risk scores). Pursuant to § 425.601(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In making this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period (referred to herein as the ''3 percent cap''). This cap is the maximum increase in prospective HCC risk scores allowed for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent. That is, the prospective HCC risk ratios (ratio of performance year risk score to the BY3 risk score) applied to historical benchmark expenditures to capture changes in health status between BY3 and the performance year will never be higher than 1.030 for any performance year over the course of the agreement period. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.[265]

The 3 percent cap was finalized through the December 2018 final rule (83 FR 68013) to address concerns with the prior approach for risk adjustment, which used a methodology that differentiated between newly assigned and continuously assigned beneficiaries, as defined in § 425.20. The issues raised by interested parties included concerns that the risk adjustment methodology did not adequately adjust for changes in health status among continuously assigned beneficiaries between the benchmark and performance years and concern that performing risk adjustment separately for newly and continuously assigned beneficiaries created uncertainty around benchmarks and made it difficult for ACOs to anticipate how risk scores would affect their financial performance (refer to 76 FR 67916 through 67919, 80 FR 32777 through 32778, 81 FR 37962 through 37968, 83 FR 68008 through 68013). As a result, in the December 2018 final rule, we finalized the use of prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period, for agreement periods beginning on July 1, 2019, and in subsequent years (83 FR 68013).

We believe that this current policy has several advantages relative to the original risk adjustment methodology distinguishing between newly and continuously assigned beneficiaries, including: allowing for some upward growth in prospective HCC risk scores between the benchmark period and the performance year for an ACO's entire assigned beneficiary population, providing better recognition for changes in beneficiary health status between the benchmark period and the performance year, and providing greater clarity for ACOs than the previous methodology, while still limiting the impact of ACO coding initiatives. However, interested parties remain concerned about the program's risk adjustment methodology, including the 3 percent cap. In the CY 2022 PFS proposed rule, we solicited comment on several issues related to the Shared Savings Program's risk adjustment methodology (86 FR 39294 and 39295)—

- Approaches, generally, to improving the risk adjustment methodology for the Shared Savings Program, and specifically for ACOs with medically complex, high cost beneficiaries.
- Approaches to risk adjustment that would balance the need for accurate and complete coding, while protecting against incentivizing coding intensity initiatives by ACO participants and ACO providers/suppliers (which may be even more problematic for ACOs with high penetration in their region) that increase risk score growth above the existing 3 percent cap.
- Alternate approaches that would increase the cap on an ACO's risk score growth in relation to risk score growth in the ACO's regional service area.
- The potential interactions between policies to remove assigned beneficiaries from the assignable beneficiary population used to calculate regional FFS expenditures and growth rates, and policies addressing regional risk score growth.

For a full summary of the comments submitted in response to our comment solicitation, we refer readers to the relevant discussion in the CY 2022 PFS final rule (86 FR 65302 through 65306). Among the comments received, many commenters expressed concern about the existing 3 percent cap on positive risk score growth, as well as the absence of a cap (or floor) on negative adjustments to account for risk score decreases. Several commenters indicated that the current 3 percent cap on risk score growth is unfair over a 5-year period, suggesting that the cap is too low over a period of this length. Additionally, several commenters suggested that the existing policy is driving inequity and may disadvantage ACOs that serve more vulnerable populations or beneficiaries with complex medical needs. Some commenters explained that beneficiaries who are in the disabled and the aged/dual eligible Medicare enrollment types are, in most combinations, more than twice as likely to have risk score growth above the cap as those who are in the aged/non-dual eligible category. These concerns are similar to certain comments made in response to the original proposal for the 3 percent cap and summarized in the December 2018 final rule (83 FR 68010 through 68012). Additionally, some commenters indicated that due to a variety of factors, such as sample size and volatility, the rates at which Medicare enrollment types are subject to the 3 percent cap on risk score growth are often significantly different. A commenter explained that there can also be significant risk score volatility when the high-risk patient population is small. This concern was also raised in response to the original proposal for the current policy (83 FR 68012). Several commenters on the proposal recommended that any cap be applied at the aggregate level rather than the enrollment type level, with one commenter suggesting that we cap the prospective HCC risk ratios in the aggregate across the four beneficiary enrollment types to account for smaller sample sizes and resulting higher volatility for certain enrollment types.

[265] Refer to the December 2018 final rule (83 FR 68007 through 68013), section on ''Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year''. See also, the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #10, February 2022), section 3.6, available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1.*

Many of the comments received in response to the comment solicitation in the CY 2022 PFS proposed rule also expressed concern that the current policy places a cap on the ACO's risk score growth but does not restrict regional risk score growth that is reflected in the regional component of the update factor, noting that this penalizes ACOs in markets where a region's risk score growth exceeds the 3 percent cap (86 FR 65304). Other commenters, notably MedPAC, expressed support for CMS' considerable caution in the area of risk adjustment, noting that population-based models can be highly susceptible to coding incentives and that the Shared Savings Program does not include a retrospective coding adjustment to offset these incentives. MedPAC recommended that CMS should address the underlying incentives for coding intensity and the accuracy of risk adjustment before considering any policy that would increase the risk score growth cap (86 FR 65304).

(2) Proposed Revisions

In response to these concerns, we considered three options to modify the existing 3 percent cap on risk score growth: (1) Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and apply the cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible); (2) Apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year; and (3) Allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, where the percentage applied would be equal to 1 minus the ACO's regional market share (continuing our consideration of the approach described in the CY 2022 PFS proposed rule (86 FR 39294)).

We believe the first two options for modifications to the risk adjustment methodology (applying the cap on risk score growth in aggregate across Medicare enrollment types, with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year) would address several of the concerns raised by interested parties by: accounting for higher volatility in prospective HCC risk scores for certain enrollment types due to smaller sample sizes; allowing for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are more frequently subject to the cap on risk score growth currently); and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. We believe the third option (to allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area) would address some commenters' concerns about the possible impacts of regional prospective HCC risk score growth, but would not address the multiple other concerns addressed by options 1 and 2. We also note that the approach described in the second option includes a component of the first option (applying the cap on an ACO's risk score growth in aggregate across Medicare enrollment types). We considered the third option independently from the first and second options, and did not consider using the third option in combination with either the first or second option. That is, we did not consider an approach under which we would account for the difference between the 3 percent cap and the risk score growth in the ACO's regional service area (third option) in combination with applying a cap on risk score growth in aggregate across Medicare enrollment types, with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year (the first and second options, respectively). We view these two approaches to be inconsistent with each other, as the third approach allows an ACO's risk score growth to rise above 3 percent based on risk score growth in the ACO's regional service area, whereas the first and second options would retain the 3 percent cap, but apply it at the aggregate level (with or without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year).

After careful consideration and modelling of the impacts of these three potential modifications to the existing 3 percent cap on positive prospective HCC risk score growth, we are proposing to use the authority granted by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other such factors as the Secretary determines to be appropriate, to modify the existing 3 percent cap on risk score growth using the first option. We are also seeking comment on the second and third options as potential alternatives to the proposed approach. We will consider the comments received on these alternative options along with the comments on our proposal to adopt the first option in the development of our final policy, and may consider adopting one of these alternatives in place of the proposed approach if we conclude that it would better address the concerns with the current risk adjustment methodology.

Under our proposal of the first option, an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points. Specifically, we would:

- Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores.
- Then apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

Demographic risk scores are based on certain demographic attributes that do not vary with the beneficiary's health condition, such as age, sex, Medicaid status, and original reason for Medicare entitlement.[266] Unlike prospective HCC risk scores, demographic risk scores are not subject to coding intensity because they do not use diagnosis information. Accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive prospective HCC risk score growth could allow for higher benchmarks than the current methodology for ACOs that have experienced increases in health risk among their assigned beneficiary populations, while still safeguarding the

[266] Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #7, February 2019), section 3.4.2, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-V7.pdf*.

Trust Funds by limiting returns due to coding initiatives. We note that the CMS Innovation Center's Global and Professional Direct Contracting (GPDC) Model, which will transition to the redesigned and renamed Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model on January 1, 2023, will also take into account the underlying demographics of a model participant's aligned beneficiary population when determining whether risk score growth will be capped starting in PY 2024.[267]

Under this proposal, the positive 3 percent cap (after accounting for changes in demographic risk scores) would also apply in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible). In other words, we would calculate a single aggregate value for the cap equal to the dollar-weighted average growth in demographic risk scores across the four enrollment types plus 3 percentage points. We would only apply this cap to risk score growth for a particular enrollment type if the aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeds the value of the cap. We believe this would make it less likely that the prospective HCC risk scores for Medicare enrollment types with smaller populations, typically populations of ESRD, disabled, or aged/dual eligible beneficiaries, would be subject to the cap. These smaller populations are more likely to experience random variation in risk score growth as a relatively small number of assigned beneficiaries with large changes in prospective HCC risk scores can have an outsized impact on the average score for the Medicare enrollment type.

To implement the new cap, we would follow these steps:

- *Step 1:* Determine demographic risk score growth for each Medicare enrollment type. Demographic risk score growth is measured as the ratio of the ACO's performance year demographic risk score for an enrollment type to the ACO's BY3 demographic risk score for that enrollment type. Before calculating these demographic risk ratios, the demographic risk scores for each enrollment type for each year would be renormalized by dividing by the national mean demographic risk score for that enrollment type for that year.
- *Step 2:* Calculate the dollar-weighted average demographic risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average demographic risk ratio. The dollar weight for each enrollment type would be equal to historical benchmark expenditures for that enrollment type divided by the sum of historical benchmark expenditures across all enrollment types. Historical benchmark expenditures for each enrollment type would be calculated as per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type. The aggregate dollar-weighted average demographic risk ratio would be computed by multiplying the risk ratio for each enrollment type by its respective dollar weight and then summing across the four enrollment types. Note that the approach of using an aggregate dollar-weighted average in this calculation would be similar to the approach used in the Shared Savings Program's original benchmarking methodology to determine whether demographic factors would be used to adjust risk scores for an ACO's continuously assigned beneficiaries.[268]
- *Step 3:* Calculate the sum of the aggregate dollar-weighted average demographic risk ratio from Step 2 and 0.030. This would represent the aggregate cap.
- *Step 4:* Determine prospective HCC risk score growth for each Medicare enrollment type. Prospective HCC risk score growth would be measured as the ratio of the ACO's performance year prospective HCC risk score for that enrollment type to the ACO's BY3 prospective HCC risk score for that enrollment type. Before calculating these prospective HCC risk ratios, the prospective HCC risk scores for each enrollment type for each year would be renormalized by dividing by the national mean prospective HCC risk score for that enrollment type for that year.
- *Step 5:* Calculate the aggregate growth in prospective HCC risk scores by calculating the dollar-weighted average prospective HCC risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average prospective HCC risk ratio, using the same dollar weights and the same approach described in Step 2.
- *Step 6:* Determine if the ACO will be subject to the cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is less than the aggregate cap determined in Step 3, no cap would apply to the prospective HCC risk ratio for any enrollment type, even if the prospective HCC risk ratio for a given enrollment type is higher than the aggregate cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is greater than or equal to the aggregate cap determined in Step 3, proceed to Step 7.
- *Step 7:* Compare the prospective HCC risk ratio for each enrollment type calculated in Step 4 to the aggregate cap determined in Step 3. If the prospective HCC risk ratio for a given enrollment type is greater than the aggregate cap, the prospective HCC risk ratio for that enrollment type would be set equal to the aggregate cap. If the prospective HCC risk ratio for a given enrollment type is less than or equal to the aggregate cap, no cap would apply to the prospective HCC risk ratio for that enrollment type.

The resulting prospective HCC risk ratios would then be multiplied by the ACO's historical benchmark expenditures for the relevant Medicare enrollment type at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year.

Table 63 provides a numeric example of this proposed methodology for a hypothetical ACO that is determined to be subject to the cap:

[267] CMS. Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model. February 24, 2022. Available at *https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model.*

[268] Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #7, February 2019), section 3.4.2, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-V7.pdf.*

TABLE 63: Example of Risk Score Calculation for Hypothetical ACO Subject to Proposed Cap

Medicare Enrollment Type	Dollar Weights	Demographic Risk Ratio	Aggregate Cap	Prospective HCC Risk Ratio (Before Cap)	Is ACO Subject to Cap?	Prospective HCC Risk Ratio (After Cap, if Applicable)
ESRD	0.050	1.035		0.980		0.980
Disabled	0.075	1.020		1.050		1.050
Aged/dual	0.080	0.990		1.089		1.056
Aged/non-dual	0.795	1.030		1.076		1.056
Weighted Average		1.026	1.056	1.070	Yes	

For this hypothetical ACO, the dollar-weighted average demographic risk ratio is 1.026, meaning that demographic risk score growth averaged across the four enrollment types was 2.6 percent from BY3 to the performance year for the ACO's assigned beneficiaries, when measured against national mean risk score growth. To calculate the cap, we would add 0.03 to this value, arriving at an aggregate cap of 1.056. This ACO is determined to be subject to the cap because its dollar-weighted average prospective HCC risk ratio of 1.070 was higher than the aggregate cap. When comparing the aggregate cap to the prospective HCC risk ratio for each individual enrollment type, risk score growth for both the aged/dual eligible and aged/non-dual eligible enrollment types would be constrained by the cap. In this example, the aggregate cap that is ultimately applied is higher than the current 3 percent cap, meaning that this hypothetical ACO would benefit from the proposed policy relative to the current policy.

In the second numeric example described in Table 64, the ACO's aggregate demographic risk ratio is less than 1 and its aggregate cap of 1.028 is less than the current effective risk score cap of 1.030. In this case, the ACO's dollar-weighted average prospective HCC risk ratio of 1.013 is below the aggregate cap meaning that no cap would be applied to the prospective HCC risk score growth for any enrollment type, even though the ACO's ESRD, disabled, and aged/dual eligible populations all have prospective HCC risk ratios above the aggregate cap. This ACO would also benefit from the proposed policy relative to the current policy, with its benefit solely stemming from the use of an aggregate cap.

TABLE 64: Example of Calculation for a Hypothetical ACO Not Subject to Proposed Cap

Medicare Enrollment Type	Dollar Weights	Demographic Risk Ratio	Aggregate Cap	Prospective HCC Risk Ratio (Before Cap)	Is ACO Subject to Cap?	Prospective HCC Risk Ratio (After Cap, if Applicable)
ESRD	0.041	1.046		1.051		1.051
Disabled	0.098	1.027		1.032		1.032
Aged/dual	0.139	1.023		1.047		1.047
Aged/non-dual	0.722	0.986		1.002		1.002
Weighted Average		0.998	1.028	1.013	No	

While the examples above show ACOs that would benefit from the proposed risk adjustment policy relative to the current policy, there are ACOs that would receive a lower updated benchmark under this proposed policy, all else being equal. Namely, ACOs with a dollar-weighted average demographic risk ratio less than 1 found to be subject to the aggregate cap (which by default, will be less than 1.030) will have their upward risk score growth constrained more by the proposed aggregate cap than the existing 3 percent cap.

We simulated the impact of this proposed policy change using performance year 2020 financial reconciliation data from ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 45 percent of ACOs would have had a higher updated benchmark with the proposed policy compared to the current policy, 5 percent would have had a lower updated benchmark with the proposed policy, and 50 percent would have been unaffected (that is, because they were not subject to any cap under either policy). Fifty-three ACOs had their prospective HCC risk ratio capped for at least one Medicare enrollment type under the proposed policy, compared to 177 ACOs under the current policy. Among ACOs that were capped under the current policy but not the proposed policy, many had prospective HCC risk score growth above 1.030 for one or more of the typically smaller enrollment types (that is, ESRD, disabled, aged/dual eligible) but not for their aged/non-dual eligible population. Table 65 illustrates that 47 percent of ACOs were subject to the current 3 percent cap imposed at the enrollment type level for one or more of the ESRD, disabled or aged/dual eligible

enrollment types versus 17 percent for aged/non-dual eligible. Under the proposed policy, the share would fall to 14 percent for both groups.

TABLE 65: Share of ACOs Subject to Actual or Proposed Risk Score Cap by Enrollment Type

	ESRD	Disabled	Aged/dual	ESRD, disabled and/or aged/dual	Aged/non-dual
Capped under Current Policy (Actual)	22%	22%	23%	47%	17%
Capped under Proposed Policy (Simulated)	5%	10%	10%	14%	14%

Based on this modeling, we believe that a significant share of ACOs would either be unaffected by or benefit from the proposed policy, especially those with increases in health risk as measured by demographic risk ratios, while a small share would do worse, likely reflecting decreases in health risk for their assigned beneficiary population as measured by demographic risk ratios. Additionally, ACOs would be much less likely to have prospective HCC risk ratios for ESRD, disabled, and aged/dual eligible Medicare enrollment types capped under this proposed policy which would improve the incentives for treating these medically complex, high cost populations. At the same time, we believe that this proposed policy would continue to be protective of the Trust Funds by continuing to limit incentives for coding intensity, as it would retain the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population.

Under the second option that we considered, we would continue to employ a fixed 3 percent cap on positive adjustments to prospective HCC risk scores, but we would apply the cap at the aggregate level. Specifically, the current 3 percent cap on risk score growth would apply in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible) instead of being applied separately for the population of beneficiaries in each Medicare enrollment type. We would only apply the current 3 percent cap on risk score growth for a particular enrollment type if the ACO's aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeds the value of the cap.

One advantage of this second, alternative option over the proposed approach, which allows aggregate prospective HCC risk score growth above 3 percent when aggregate demographic risk score growth is positive, is that no ACOs would receive a lower updated benchmark under this methodology compared to the current approach. However, according to our simulations using performance year 2020 financial reconciliation data from ACOs in agreement periods beginning on or after July 1, 2019, while around 5 percent of ACOs would have had higher benchmarks under this second, alternative approach compared to the proposed approach, around 12 percent would have had lower benchmarks under this approach compared to the proposed approach. Thus, we believe that this second, alternative approach would, in aggregate, be less advantageous to ACOs than the proposed approach.

Under the third option that we considered, which we also described in the CY 2022 PFS proposed rule (86 FR 39294), we would allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area. The percentage applied would be equal to 1 minus the ACO's regional market share. For example, if regional risk score growth for a particular enrollment type was 5 percent and the ACO's regional market share was 20 percent, we would increase the cap on the ACO's risk score growth for that enrollment type by an amount equal to the difference between the regional risk score growth and the existing cap (2 percent) multiplied by one minus the ACO's regional market share (80 percent). Thus, the ACO would face a cap for this enrollment type equal to 4.6 percent instead of 3 percent (3 percent + (2 percent × 80 percent)). This approach would raise the existing cap while limiting the ability for ACOs with high penetration in their regional service areas to increase their cap by engaging in coding intensity initiatives that significantly raise their regions' prospective HCC risk scores. While this third, alternative option could potentially mitigate concerns raised by some commenters about the impacts of regional prospective HCC risk score growth, modeling suggested that relatively fewer ACOs would benefit under this alternative approach as compared to the proposed methodology incorporating demographic risk score growth. A key reason for this is that a relatively small share of ACOs affected by the existing 3 percent cap on risk score growth operated in regional service areas where regional risk score growth was greater than 3 percent.

Furthermore, we still have concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those highly penetrated in their regional service areas, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. We believe that our proposed methodology would avoid this undesired incentive while still accounting for changes in health risk for an ACO's assigned beneficiary population to a greater extent than the current policy and would also help to address cases where regional risk score growth stems from higher volatility due to small sample sizes or shifting demographics within a regional service area.

Our modeling suggests that a majority of ACOs that operate in regions with risk score growth in excess of 3 percent for at least one Medicare enrollment type would have had a higher updated benchmark under the proposed policy than the current policy. In addition, we believe that our proposal to incorporate a prospective, external factor in the growth rates used to update the historical benchmark (see section III.G.5.c.(3) of this proposed rule) would further help to mitigate concerns raised by some commenters about the impacts of regional risk score growth, by decreasing the weight placed on the two-way blend of national and regional growth rates when updating an ACO's

historical benchmark for each performance year in the ACO's agreement period.

Although requested by some commenters, we decline to consider an approach that would limit the impact of prospective HCC risk score decreases at this time. As we have described in past rulemaking (83 FR 68011), we remain concerned that such approach would encourage favorable risk selection. If ACOs seek to attract low-cost beneficiaries or avoid high-cost beneficiaries, they could lower their performance year expenditures without any corresponding adjustment to their benchmark due to the cap on negative prospective HCC risk adjustments. We continue to believe that this effect would be detrimental to medically complex patients, who may miss the opportunity to receive better coordinated care through an ACO, as well as to the Medicare Trust Funds. We also decline to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area, as requested by some commenters as we are concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs that are highly penetrated in their regional service areas. Currently, ACOs that are highly penetrated in their regional service area have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. Capping risk score growth in an ACO's regional service area could change the incentives and encourage ACOs to engage in coding initiatives.

We propose to revise the regulations governing risk adjustment under the BASIC track and the ENHANCED track at § 425.605(a)(1) and § 425.610(a)(2), respectively, to reflect the proposed modifications to the risk adjustment methodology.

We seek comment on the proposed changes to the risk adjustment methodology for agreement periods beginning on or after January 1, 2024. While we believe that the modifications that we are proposing to the program's risk adjustment methodology in conjunction with other policies we are proposing in this proposed rule would provide the best balance between addressing concerns raised by interested parties and limiting incentives for coding intensity and risk selection, we also seek comment on the two alternatives considered. We will consider the comments received on these alternative options along with the comments on our proposed changes to the risk adjustment methodology, and may consider adopting one of these alternatives in place of the proposed approach if we conclude that it would better address the concerns with the current risk adjustment methodology.

f. Increased Opportunities for Low Revenue ACOs to Share in Savings

(1) Background

In the November 2011 final rule (76 FR 67927 through 67929), we explained that a goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards. However, we also acknowledged that observed savings can also occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. Thus, even if an ACO engages in no activities to improve the quality and efficiency of the services it delivers, in certain cases, differences between the benchmark expenditures and assigned patients' expenditures would be observed during some performance periods merely because of such normal variation. Consequently, section 1899(d)(1)(B)(i) of the Act requires us to specify an MSR to account for the normal variation in expenditures, based upon the number of Medicare FFS beneficiaries assigned to the ACO. As we stated in the November 2011 final rule, the MSR should be set in a way that gives us some assurance that the ACO's performance is a result of its interventions, not normal variation in expenditures. However, we also do not want an outcome where savings that have been earned are not recognized.

Establishing an MSR on the basis of standard inferential statistics that take into account the size of an ACO's beneficiary population provides confidence that, once the savings achieved by the ACO exceed the MSR, the change in expenditures represents actual performance improvements by the ACO as opposed to normal variations. There are several policy implications associated with the methodology used to set the MSR. A higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieving savings, a higher MSR could also discourage potentially successful ACOs, especially physician-organized ACOs and smaller ACOs in rural areas, from participating in the program. In contrast, a lower MSR would encourage more potential ACOs to participate in the program, but would also provide less confidence that shared saving amounts are a result of improvements in quality and efficiency made by an ACO. In the original rulemaking establishing the Shared Savings Program, we stated that we believed that the most appropriate policy concerning determination of the ''appropriate percent'' for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds. In the November 2011 final rule, we finalized an approach wherein the MSR and MLR are calculated as a percentage of the ACO's updated historical benchmark (see §§ 425.604(b) (Track 1), 425.606(b) (Track 2)).

In the June 2015 final rule, we finalized an approach to offer Track 2 ACOs and ACOs in the new Track 3 (subsequently renamed the ENHANCED track) the opportunity to select the MSR/MLR that will apply for the duration of the ACO's 3-year agreement period from several symmetrical MSR/MLR options (80 FR 32769 through 32771, and 80 FR 32779 and 32780; §§ 425.606(b)(1)(ii) and 425.610(b)(1)). We explained our belief that offering ACOs a choice of MSR/MLR will encourage ACOs to move to two-sided risk, and that ACOs are best positioned to determine the level of risk they are prepared to accept. For instance, ACOs that are more hesitant to enter a performance-based risk arrangement may choose a higher MSR/MLR, to have the protection of a higher threshold before the ACO would become liable to repay shared losses, thus mitigating downside risk, although the ACO would in turn be required to meet a higher threshold before being eligible to receive shared savings. ACOs that are comfortable with a lower threshold of protection from risk of shared losses may select a lower MSR/MLR to benefit from a corresponding lower threshold for eligibility for shared savings. We also explained our belief that applying the same MSR/MLR methodology in both of the risk-based tracks reduces complexity for CMS' operations and establishes more equal footing between the risk models. ACOs participating in the Track 1+ Model were also allowed

the same choice of MSR/MLR to be applied for the duration of the ACO's agreement period under the Track 1+ Model.[269]

ACOs applying to a two-sided model (Track 2, Track 3 or the Track 1+ Model) could select from the following options:

- Zero percent MSR/MLR.
- Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.
- Symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under § 425.604(b) for Track 1. The MSR is the same as the MSR that would apply in the one-sided model, and the MLR is equal to the negative MSR.

In the December 2018 final rule, we finalized policies governing the MSR/MLR for ACOs in the BASIC track at § 425.605(b). Under the final policies, ACOs in a one-sided model of the BASIC track's glide path have a variable MSR based on the number of beneficiaries assigned to the ACO (§ 425.605(b)(1)). The variable MSR (ranging from 3.9 percent for ACOs with 5,000 assigned beneficiaries to 2.0 percent for ACOs with 60,000 or more assigned beneficiaries) is determined using the same methodology that was used for Track 1. ACOs in a two-sided model of the BASIC track are able to choose among the MSR/MLR options that are available to ACOs in the ENHANCED track. ACOs participating under Level A or B of the BASIC track's glide path will choose an MSR/MLR, ranging from zero to 2 percent (in 0.5 percent increments), or that is variable based on number of beneficiaries assigned to the ACO, before the start of their first performance year in a two-sided model (§ 425.605(b)(2)(i)). This selection will occur before the ACO enters Level C, D or E of the BASIC track's glide path, depending on whether the ACO is automatically transitioned to a two-sided model (Level C or E) or elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E), and will be in effect for the duration of the agreement period that the ACO is under two-sided risk (§ 425.605(b)(2)(ii)).

In addition to the MSR/MLR, we also use an ACO's quality score as part of the determination of eligibility for and calculation of shared savings and shared losses. In the CY 2021 PFS final rule, we adopted a new regulation at § 425.512(a) to reflect the new quality performance requirements under the Shared Savings Program for performance year 2021 and subsequent performance years. For performance years beginning on January 1, 2021, and subsequent performance years, if the ACO meets the quality performance standard established under § 425.512, the ACO will share in savings at the maximum sharing rate based on the ACO's track/level of participation (refer to Table 66). The final sharing rate is applied to an ACO's savings on a first dollar basis up to the applicable performance payment limit, expressed as a percentage of the ACO's updated benchmark.

TABLE 66: Maximum Sharing Rate by Track

	BASIC Track's Glide Path				ENHANCED Track (risk/reward)
	Level A & B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once MSR met or exceeded)*	1st dollar savings at a rate of 40% if quality performance standard is met; not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 50% if quality performance standard is met, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of 75% if quality performance standard is met, not to exceed 20% of updated benchmark.

* For BASIC Track Levels A and B refer to § 425.605(d)(1)(i) and (d)(1)(ii), for Levels C, D, and E refer to § 425.605(d)(1)(iii)(A) and (B), (d)(1)(iv)(A) and (B), and (d)(1)(v)(A) and (B), and for the ENHANCED Track refer to § 425.610 (d) and (e).

As discussed in the November 2011 final rule and during subsequent rulemaking cycles, we have received comments from ACOs and other interested parties expressing concerns regarding the MSR/MLR methodology and proposing revisions. Commenters responding to the April 2011 proposed rule [270] expressed concern that the proposed (and later finalized) methodology for establishing the MSR on a sliding scale based on population size would disadvantage smaller ACOs, including ACOs likely to form in rural areas and those largely comprised of small- and medium-sized physician practices, and discourage their participation by setting too high a bar on shared savings (76 FR 67928 and 67929). Some commenters considered the potential long-term consequences of this dynamic, indicating it could ultimately result in diminished provider competition in some markets or stifle the development of innovative care coordination strategies. Further, as other commenters indicated, smaller ACOs are likely to be in greatest need of additional capital to support start-up and operational expenses. Some commenters suggested that the MSRs that apply to smaller ACOs based on their number of assigned beneficiaries may make it impossible for these ACOs to ever share in savings.

Additionally, a number of commenters offered that other proposed policies under the Shared Savings Program, including, for example, the

[269] Refer to the Medicare ACO Track 1+ Model Participation Agreement, section V, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

[270] The proposed rule proposing the establishment of the Shared Savings Program entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' appeared in the April 7, 2011 **Federal Register** (76 FR 19528) (herein referred to as the ''April 2011 proposed rule'').

rigorous quality performance standards and the requirement that all ACOs ultimately accept downside performance risk, are sufficient to ensure savings are a result of actions by ACOs and obviate the need for an MSR. One commenter suggested a blended approach such that if an ACO exceeds the 2 percent MSR, it would be eligible for a lower sharing rate, but would not receive the full sharing rate unless it exceeded its statistically adjusted MSR.

In the December 2018 final rule (83 FR 67924 through 67928), we summarized commenters' responses to the proposals described in August 2018 proposed rule related to the MSR and MLR. One commenter asked that CMS reconsider its proposals in order to ''lessen restrictions and remove barriers to participation in risk sharing arrangements,'' but did not specify which aspects of the MSR/MLR proposals they believed to be restrictive or to create barriers. A number of commenters supported a combination of a lower MSR and higher sharing rates for low revenue ACOs participating in the BASIC track and offered several different alternatives. Commenters explained that combining a lower MSR and higher final sharing rate was necessary to ensure there are sufficient and attainable incentives to support ACOs' efforts to improve quality and lower cost, to provide early returns on investments as well as predictability of savings and the financial support ACOs need to ensure successful participation, and to incentivize low revenue and physician-led ACOs to participate in the redesigned participation options under the Shared Savings Program.

While it remains important to ensure performance payments are not based on normal expenditure fluctuations, we believe modification to our MSR policy would provide payments to ACOs with the greatest need for shared savings, in particular smaller, rural ACOs which tend to be less capitalized, allowing for investments in care redesign and quality improvement activities. This modification would also align with the other changes we are proposing to the participation options and financial methodologies under the Shared Savings Program to encourage participation by new ACOs and ACOs that focus on underserved populations, such as the proposal to offer AIPs to new low revenue ACOs joining the BASIC track as described in section III.G.2. of this proposed rule.

(2) Proposed Revisions

We are proposing to use our authority under section 1899(i)(3) of the Act, for the use of other payment models, to expand the eligibility criteria to qualify for shared savings to enable certain low revenue ACOs participating in the BASIC track to share in savings even if the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act. Specifically, we are proposing to modify the relevant provisions of § 425.605 to specify that ACOs participating in the BASIC track that do not meet the MSR requirement, but do meet the quality performance standard or the proposed alternative quality performance standard under § 425.512 and otherwise maintain eligibility to participate in the Shared Savings Program, would qualify for a shared savings payment if the following criteria are met:

- The ACO has average per capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark.
- The ACO is a low revenue ACO as defined in § 425.20 at the time of financial reconciliation for the relevant performance year.
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard required to share in savings at the maximum sharing rate would receive half of the maximum sharing rate for their level of participation (20 percent instead of 40 percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate but meet the proposed alternative quality performance standard, the sharing rate would be further adjusted according to the proposal described in section III.G.4.b. of this proposed rule, which would reinstate a sliding scale approach for determining shared savings. This calculation would use an ACO's quality performance score, which would reflect the inclusion of health equity adjustment bonus points as proposed in section III.G.4.b.(7) of this proposed rule, if finalized. A numerical example is provided in Table 67.

TABLE 67: Numerical Example of Proposed Modification to BASIC Track Sharing Rates for Eligible ACOs

Track	BASIC Track, Level E
Total Benchmark Expenditures	$150,000,000
Total Performance Year Expenditures	$149,850,000
Total Benchmark Expenditures minus Total Performance Year Expenditures (Savings)	$150,000
Savings as a Percent of Benchmark	0.1%
Minimum Savings Rate	2%
Maximum Sharing Rate	50%
Health Equity Adjusted Quality Performance Score	45%
Met Criteria in Quality Performance Standard for Maximum Sharing Rate?	No
Met Quality Performance Standard for Scaled Sharing Rate?	Yes
Earned Performance Payment (before sequestration and application of shared savings limit)	
Current Policy	$0
Proposed Policy	(½ * 50%) * 45% * $150,000 = $16,875

This approach would apply to low revenue ACOs entering an agreement period in the BASIC track beginning January 1, 2024, and in subsequent years. High revenue ACOs in the BASIC track, ACOs below 5,000 assigned beneficiaries at the time of financial reconciliation, and ACOs in the ENHANCED track would not be eligible for this option. We are proposing that this policy would apply to all ACOs meeting the criteria, including new, renewing, and re-entering ACOs, in order to provide incentives both for new ACOs to join the Shared Savings Program and for existing ACOs to remain in the program. This differs from the proposed eligibility criteria for AIPs listed in section III.G.2.a.(2) of this proposed rule, which are limited to ACOs that are new to the Shared Savings Program with the intent of lowering barriers to entry. Although as described in section III.G.2.b.(2) of this proposed rule we are proposing to revise our regulations to permit otherwise eligible ACOs that are inexperienced with performance-based risk Medicare ACO initiatives to elect to participate in one, 5-year agreement period under a one-sided model of the BASIC track's glide path regardless of revenue status, we believe it would be appropriate to limit this proposed policy change to the low revenue ACOs in the BASIC track in order to direct the payments to ACOs with the greatest need for capital, in particular smaller, rural ACOs which tend to be less capitalized, allowing for investments in care redesign and quality improvement activities. We do not believe it is necessary or appropriate to extend this opportunity to high revenue ACOs as these ACOs, which tend to include institutional providers and are typically larger and better capitalized, have the potential to exert more influence, direction, and coordination over the full continuum of care, and thus have a greater potential to achieve the level of savings necessary to meet the MSR. We believe that by retaining the requirement that high revenue ACOs meet or exceed their MSR, we will drive more meaningful systematic change by the ACOs that have the greatest potential to achieve significant change in spending. Furthermore, we note that our proposal to exclude ACOs with fewer than 5,000 assigned beneficiaries at the time of financial reconciliation aligns with the requirement under section 1899(b)(2)(D) of the Act and § 425.110 that an ACO have at least 5,000 assigned beneficiaries and guards against the heightened risk—absent an MSR—that any savings are the result of random variation.

We simulated the impact of this proposal using financial reconciliation data from performance years 2020, 2019, and 2019A.[271] There were 80, 109, and 60 positive within corridor ACOs (that is, ACOs that had performance year expenditures below benchmark expenditures but did not meet the MSR and did not receive shared savings payments) in each year, respectively. Of these positive within corridor ACOs, 35 ACOs in 2020 and 2019 and 18 ACOs in 2019A would have met the criteria described in this section and received a shared savings payment under our proposed policy change. On average, the positive within corridor ACOs that would benefit from the proposed policy change had fewer assigned beneficiaries in all 3 performance years and a larger share of these ACOs were classified as rural in performance years 2020 and 2019.[272] We believe by offering additional opportunities for low revenue ACOs to share in savings, this proposed approach could increase participation in the Shared Savings Program by providing an incentive for new ACOs to join the program and for existing ACOs to remain in the program. In addition, this proposal would enable low revenue ACOs, which are most in need of additional capital, to make investments in care redesign and quality improvement activities, and would also recognize incremental improvements in care by ACOs that receive AIPs.

To exercise our authority under section 1899(i) of the Act, we must determine that a payment model under which certain low revenue ACOs participating in the BASIC track may

[271] Performance year 2019 refers to both the 12-month performance year from January 1, 2019 through December 31, 2019 and the 6-month performance year from January 1, 2019 through June 30, 2019. Performance year 2019A refers to the 6-month performance year from July 2, 2019 through December 31, 2019.

[272] For this analysis, ACOs were classified as rural if the plurality of their assigned beneficiaries resided in either micropolitan or noncore counties as defined by The United States Census Bureau and the Office of Management and Budget (OMB).

qualify for shared savings payments even when the MSR as required under 1899(d)(1)(B)(i) is not met, will improve the quality and efficiency of items and services furnished under the Medicare program, and that program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. By supporting expanded and sustained participation by ACOs in the Shared Savings Program, we believe this proposed approach would allow for lower growth in Medicare FFS expenditures. We also believe this proposed approach would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs would have an incentive to perform well on quality measures in order to maximize the shared savings they may receive. Further, the proposed approach would provide additional capital to enable low revenue ACOs to make investments in care redesign and quality improvement activities, potentially leading to improvements in the quality and efficiency of items and services furnished to Medicare FFS beneficiaries. We also believe this proposal, along with many of the other proposals in this proposed rule, would expand participation among ACOs serving higher cost beneficiaries for whom the savings potential is greater (relative to ACOs serving lower cost beneficiaries that may already find the current regional adjustment methodology an adequate incentive to participate in the program), and among low revenue ACOs, which have historically performed well in the program. For example, in performance year 2018, about 49 percent of low revenue Shared Savings Program ACOs shared in savings compared to 28 percent of high revenue ACOs. These proportions were 63 percent and 40 percent in PY 2019, 69 percent and 40 percent in PY 2019–A, and 75 percent and 59 percent in PY 2020.[273] Lastly, as discussed in the Regulatory Impact Analysis (see section VII. of this proposed rule), this proposed change is not expected to result in a situation in which all policies adopted under the authority of section 1899(i) of the Act, when taken together, result in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

[273] Refer to *Data.CMS.gov,* Performance Year Financial and Quality Results, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results/data.*

We are proposing to amend the regulation at § 425.605, which governs calculation of shared savings and shared losses under the BASIC track, to specify an exception to the MSR requirement for eligible ACOs participating in an agreement period beginning on January 1, 2024, and in subsequent years, in a new provision at § 425.605(h). We are also proposing modifications to the provisions in § 425.605(d)(1) specifying the calculation of the final sharing rate for the different levels of the BASIC track. Further we are proposing conforming changes to §§ 425.100(b)(1), 425.605(a), 425.605(b)(3), and 425.605(c)(2) to reflect this exception to the MSR requirement.

We seek comment on this proposal to expand the criteria ACOs can meet to qualify for shared savings under the BASIC track.

g. Ongoing Consideration of Concerns About the Impact of the Public Health Emergency (PHE) for COVID–19 on ACOs' Expenditures

On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19 (hereafter referred to as the PHE for COVID–19). On March 11, 2020, the World Health Organization (WHO) publicly characterized COVID–19 as a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 outbreak a national emergency. The term ''Public Health Emergency,'' as defined in the regulation at § 400.200, identifies the PHE determined to exist nationwide as of January 27, 2020, by the Secretary under Section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals. This determination was, as of this publication, subsequently renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, and April 12, 2022. In the March 31st COVID–19 IFC (85 FR 19267 and 19268) and the May 8th COVID–19 IFC (85 FR 27573 through 27587) we adopted several modifications to policies under the Shared Savings Program in response to the PHE.

In the March 31st COVID–19 IFC (85 FR 19267 and 19268), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances (EUC) policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may have been unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19.

In the May 8th COVID–19 IFC (85 FR 27573 through 27587), we modified certain Shared Savings Program policies to: (1) allow ACOs whose current agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1 year; (2) allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (3) adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication.

As discussed in the May 8th COVID–19 IFC (85 FR 27578 through 27582) and in accordance with § 425.611, all Parts A and B fee-for-service (FFS) payment amounts for an episode of care for treatment of COVID–19 are excluded from the following Shared Savings Program calculations:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures.
- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

As part of the March 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Medicare sequestration adjustments were

temporarily suspended. This suspension has been further extended through subsequent legislation. Most recently, the Protecting Medicare and American Farmers from Sequester Cuts Act extended the suspension through March 31, 2022. From April 1, 2022, to June 30, 2022, sequestration will be 1 percent. Starting July 1, 2022, sequestration will increase to 2 percent. When full Medicare sequestration is in effect, we are required to make a 2 percent reduction to shared savings payments that is applied before applying an ACO's shared savings limit. As a result of the suspension of sequestration in 2020 and 2021, shared savings payments made in 2020 and 2021 were roughly 2 percent higher than they would have been otherwise for ACOs that did not earn shared savings in excess of their shared savings limit.

In December 2017, we issued an interim final rule with comment period entitled ''Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the ''December 2017 IFC''), which appeared in the **Federal Register** on December 26, 2017 (82 FR 60912 through 60919). In the December 2017 IFC, we established a policy for mitigating shared losses for Shared Savings Program ACOs participating in a performance-based risk track, when the ACO's assigned beneficiaries were located in geographic areas that were impacted by extreme and uncontrollable circumstances, such as hurricanes, wildfires, or other triggering events, during PY 2017. In the CY 2019 PFS final rule (83 FR 59707), we extended the extreme and uncontrollable circumstances policy finalized for PY 2017 to PY 2018 and subsequent performance years. We apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected areas. Further, we have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

The Secretary's declaration of the PHE for COVID–19 in January 2020 triggered the Medicare Shared Savings Program's Extreme and Uncontrollable Circumstances Policy. The extreme and uncontrollable circumstances of the PHE for COVID–19 began in January 2020, and will apply nationwide for the duration of the PHE for COVID–19. As set forth in §§ 425.605(f) (applicable to ACOs in two-sided models of the BASIC track) and 425.610(i) (applicable to ACOs in the ENHANCED track), we reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. The PHE for COVID–19 was considered an extreme and uncontrollable circumstance that applied to all counties in the United States for the entirety of PY 2020 and PY 2021, and no ACOs were liable for shared losses for those performance years as any such losses were fully mitigated by the adjustment for extreme and uncontrollable circumstances.

As a result of forgoing the 2021 application cycle for new applications, agreement periods starting in 2022 are the first agreement periods for which 2020 and 2021 serve as benchmark years for ACOs in the Shared Savings Program. Interested parties have expressed concern that the policy adjustments made in response to the PHE for COVID–19 may not fully address the potential for relatively lower expenditures resulting from lower utilization by non-COVID–19 patients. For example, in 2020, Parts A and B FFS expenditures decreased by 7 percent nationally compared to 2019. This decrease in utilization and expenditures could result in relatively lower benchmark year expenditures for ACOs in agreement periods beginning in 2022, 2023 or 2024 for which 2020 and/or 2021 are benchmark years. Several interested parties have suggested alternative approaches to establishing benchmarks for ACOs for which 2020 and 2021 are benchmark years, including using alternative years (such as 2017, 2018, and 2019), or differently weighting COVID–19 affected years in the calculation of financial benchmarks. The impact of COVID–19 was not uniform for all areas of the country as surges occurred in different geographic areas at different times. Removing specific years from benchmark calculations would have varied effects on different geographic areas depending on when COVID–19 had the largest impact in those areas. We believe such approaches could produce mixed results; one analysis performed by the Institute for Accountable Care [274] estimated that 55 percent of ACOs would have lower benchmarks if 2020 were dropped from the benchmark period.

OACT's analysis of current data indicates that ACOs exhibiting sharp declines in spending in 2020 tend to show rebounds in spending in 2021 such that historical benchmarks averaged across a base period including both 2020 and 2021 would appear to represent a reasonable basis from which to update ACO spending targets going forward. Due to the rebound in 2021 national expenditures, which increased by roughly 8.4 percent between 2021 Q1 (lowest observed expenditures since the PHE for COVID–19 began) and 2021 Q4, we believe that the current blended national-regional trend and update factors will be sufficient to address and mitigate the impact of the start of the PHE for COVID–19 on benchmark year expenditures. ACOs that did not experience such an increase in spending between 2021 Q1 and 2021 Q4 would still be subject to a regional adjustment that could beneficially impact their benchmark determination. The proposal described in section III.G.5.c.(3) of this proposed rule to utilize a three-way blend of the ACPT/national-regional growth rates to update benchmarks would further mitigate any potential adverse effects of the PHE for COVID–19 on historical benchmarks while also protecting against unanticipated variation in performance year expenditures and utilization resulting from a future PHE. We seek comment on this analysis regarding the impact of the PHE for COVID–19 on Shared Savings Program ACOs' expenditures. In addition, we will continue to monitor the impact of the PHE for COVID–19 to determine whether any further changes may be necessary to account for the effects of this PHE or future PHEs.

h. Proposed Supplemental Payment for Indian Health Service and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in the December 2018 final rule (83 FR 67856 and 67857), we exclude Indirect Medical Education (IME), Disproportionate Share Hospital (DSH) and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations because we do not wish to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking (76 FR 67919 through 67922, and 80 FR 32796 through 32799).

[274] Institute for Accountable Care. Analysis of Policy Options to Reduce the Impact of COVID–19 on ACO Benchmarks. October 13, 2021. Available at *https://www.institute4ac.org/covid-19-aco-benchmarks-analysis/*.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28396 through 28398), we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. As explained in the FY 2023 IPPS/LTCH PPS proposed rule, we have determined that this supplemental payment is necessary to avoid causing undue long-term financial disruption to IHS/Tribal hospitals and hospitals located in Puerto Rico as a result of a proposed change in the data used to determine uncompensated care payments for these hospitals beginning in FY 2023.

In order to align Shared Savings Program policies with updates made to Medicare FFS payment policies, we are proposing to exclude this supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, if the proposal to establish this new supplemental payment is finalized in the FY2023 IPPS/LTCH PPS final rule. Further, for consistency with our current approach of using total revenue, including IME, DSH and uncompensated care payments, in Shared Savings Program calculations of ACO participant revenue,[275] we propose to similarly include the proposed supplemental payment to IHS/Tribal hospitals and hospitals located in Puerto Rico in such calculations for the performance year beginning January 1, 2023, and subsequent performance years. More specifically, ACO participant revenue is used in determining whether an ACO is a low revenue ACO or high revenue ACO as defined in § 425.20, and in determining the revenue-based loss sharing limits under two-sided models of the BASIC track's glide path in accordance with § 425.605. Because this proposed new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico is intended to prevent disruptions due to a change in the uncompensated care payment methodology for these hospitals and uses these hospitals' FY 2022 uncompensated care payments as the starting point for this calculation, we believe that it should be treated consistently with how we currently treat uncompensated care payments in Shared Savings Program calculations. We seek comment on this proposed change to the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, including the determination of benchmark and performance year expenditures, as well as the calculation of ACO participant revenue.

In the November 2011 final rule (76 FR 67919), we explained that section 1899(d) of the Act provides flexibility to adjust the benchmark for IME and DSH payments, and certain other adjustments to Parts A and B payments. Section 1899(d)(1)(B)(ii) of the Act states, among other things, that the benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate. However, when it comes to performance year expenditures, section 1899(d)(1)(B)(i) of the Act provides authority to adjust expenditures in the performance period for beneficiary characteristics, but does not provide authority to adjust for ''other factors.'' Thus, we noted that while we could make some adjustments to the benchmark pursuant to section 1899(d)(1)(B)(ii) of the Act, to exclude certain payments, we could not make similar adjustments in our calculation of performance year expenditures. In the November 2011 final rule (76 FR 67921 and 67922), we adopted an alternate payment methodology that excluded IME and DSH payments from ACO benchmark and performance year expenditures, as authorized by section 1899(i) of the Act. We have maintained this approach to excluding IME and DSH payments across all Shared Savings Program calculations of benchmark and performance year expenditures, as specified in 42 CFR part 425, subpart G.

Consistent with our longstanding policy with respect to excluding IME and DSH payments from benchmarking and performance year expenditures, we are proposing to use our authority under section 1899(i)(3) of the Act to use other payment models to remove the proposed supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures. To exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model would improve the quality and efficiency of items and services furnished under the Medicare program and that program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. Because we are proposing to exclude the supplemental payment from benchmark year expenditures using our authority under section 1899(d)(1)(B)(ii) of the Act, removing this payment from performance year expenditures would ensure greater parity between benchmark and performance year expenditure calculations. Further, by removing the proposed supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures we can reward more accurately actual decreases in unnecessary utilization of health care services. Excluding supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditure calculations ensures these payments do not make it more challenging for an ACO to generate shared savings as compared to its updated historical benchmark. We also note that, for ACOs participating under two-sided models of the BASIC track's glide path, excluding the supplemental payment from performance year expenditures may help to mitigate the amount of losses generated by an ACO, although including the supplemental payment in the calculation of ACO participant revenue used to determine the revenue-based loss sharing limit may result in a relatively higher loss sharing limit used in determining an ACO's shared losses.

Considering the balance of these factors we believe that the proposed approach could help ensure participation of IHS/Tribal hospitals and hospitals located in Puerto Rico in ACOs, and their engagement in the accountable care model. In turn, this could result in Medicare beneficiaries receiving higher quality, better coordinated and more cost-efficient care in these settings. We also do not expect that excluding the proposed new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures will result in greater payments to ACOs than would otherwise have been made if this proposed new supplemental payment were included. We will continue to reexamine this policy in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would

[275] In the December 2018 final rule, see for example the discussion of the calculation of ACO participant revenue as used in the determining the revenue-based loss sharing limits under the BASIC track (83 FR 67856) and the determination of whether an ACO qualifies as a low revenue ACO or a high revenue ACO (83 FR 67875).

undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We propose to modify the provisions of the existing regulations describing calculations of benchmark year and performance year expenditures to incorporate a reference to the exclusion of the proposed new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, if finalized, for the performance year beginning January 1, 2023, and subsequent performance years, and to include this exclusion in proposed new sections of the regulations as follows:

- Within § 425.601(a)(1)(i) and the proposed new section of the regulations at § 425.652(a)(1)(i), specifying the calculation of payment amounts included in Parts A and B FFS claims using a 3-month claims run out with a completion factor, for computing per capita Medicare Part A and B benchmark expenditures for beneficiaries that would have been assigned to ACO in any of the 3 most recent years prior to the start of the agreement period.
- Within § 425.601(c)(2)(i) and the proposed new section of the regulations at § 425.654(a)(2)(i), specifying the calculation of county-level assignable beneficiary expenditures using payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor.
- Within § 425.605(a)(5)(i), describing the calculation of performance year expenditures under the BASIC track using payment amounts included in Medicare Parts A and B FFS claims for the ACO's assigned beneficiary population for the performance year.
- Within § 425.610(a)(6)(i), describing the calculation of performance year expenditures under the ENHANCED track using payment amounts included in Medicare Parts A and B FFS claims for the ACO's assigned beneficiaries for the performance year.
- Within the proposed new section of the regulations at § 425.660(b)(1)(i), describing the calculation of the ACPT.

i. Organization and Structure of the Regulations Text Within 42 CFR Part 425 Subpart G; Technical and Conforming Changes

Since the Shared Savings Program was established in 2012, the benchmarking methodology has been specified in several sections of the Shared Savings Program regulations within 42 CFR part 425, subpart G. Section 425.601 specifies the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years. Sections 425.602 and 425.603 specify the benchmarking methodology applicable to earlier agreement periods for new and renewing ACOs, respectively. To date, we have tended to include the entirety of the benchmarking methodology applicable to ACOs, based on their agreement period start date, within a single section of the regulations. However, there are currently a limited number of unused sections within the range between §§ 425.600 and 425.613, and no remaining sections in sequential order immediately following the existing benchmarking sections.

A variety of other provisions are contained within subpart G. Specifically, § 425.600 specifies selection of risk models. The methodology for calculation of shared savings or losses (as applicable) under each of the Shared Savings Program's financial models is specified within §§ 425.604 (Track 1), 425.605 (BASIC track), 425.606 (Track 2), and 425.610 (ENHANCED track). Several sections specify particular requirements or exceptions relating to determining performance for ACOs in earlier performance years: § 425.608 applied to determine first year performance for ACOs beginning their participation in the program on April 1 or July 1, 2012; and § 425.609 applied to determine performance for a 6-month performance year (or performance period) during CY 2019. Section 425.611 specifies adjustments to Shared Savings Program calculations to address the COVID–19 pandemic. Section 425.612 specifies waivers of payment rules and other Medicare requirements, including the SNF 3-day rule waiver, and § 425.613 addresses expanded use of telehealth services furnished by physicians or other practitioners participating in applicable Shared Savings Program ACOs.

We have considered how to restructure the regulations to incorporate the proposed modifications to the benchmarking methodology in this proposed rule. One consideration is that the existing provisions of the regulations under subpart G are referred to within programmatic material, including guidance and technical specifications documents. For continuity and clarity, we believe it is important to maintain the organization of the existing provisions, as opposed to renumbering these existing sections. We also considered the need for a regulations text structure that would organize the details for the multiple aspects of the benchmarking calculations, each of which is detailed and complex. Lastly, as discussed in section III.G.2. of this proposed rule, we are proposing to specify the policies governing the proposed AIPs in a new section of the regulations at § 425.630. For these reasons, we are proposing to specify the proposed modifications to the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years in a series of new regulations at §§ 425.650 through 425.660. We propose the following organization and structure for subpart G of the regulations:

- Reserve sections §§ 425.614 through 425.629, prior to the proposed new section of the regulations at § 425.630 on the option to receive AIPs.
- Reserve sections §§ 425.631 through 425.649.
- Establish a new section of the regulations at § 425.650, generally describing the organization of the sections on the benchmarking methodology within 42 CFR part 425, subpart G.
- Establish a new section of the regulations at § 425.652 which specifies the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.
- Establish a new section of the regulations at § 425.654, which specifies the methodology for calculating county expenditures and regional expenditures for agreement periods beginning on January 1, 2024, and in subsequent years.
- Establish a new section of the regulations at § 425.656, which specifies the methodology for calculating the regional adjustment to the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.
- Establish a new section of the regulations at § 425.658, which specifies the methodology for calculating the prior savings adjustment to the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.
- Establish a new section of the regulations at § 425.660, which specifies the methodology for calculating the ACPT used in updating the historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

We also propose to make certain technical and conforming changes to the following provisions to reflect our proposal to add new regulations at

§§ 425.652 through 425.660 to establish the benchmarking methodology applicable to all agreement periods starting on January 1, 2024, and in subsequent years.

• Under subpart C, which governs application procedures, add a reference to § 425.652 in § 425.204(g).

• Under subpart G, which governs shared savings and losses calculations, do the following—

++ In § 425.600(f)(4), add a reference to § 425.656(d) in § 425.600(f)(4)(ii) and a reference to § 425.652(c) in § 425.600(f)(4)(iii);

++ Revise § 425.601 to specify that it applies to agreement periods beginning on or after July 1, 2019, and before January 1, 2024;

++ Add references to § 425.652 in §§ 425.605(a), 425.605(a)(2), 425.605(d)(1)(iii)(D)(*2*), 425.605(d)(1)(iv)(D)(*2*), 425.605(d)(1)(v)(D)(*2*), 425.610(a), and 425.610(g);

++ Add reference to § 425.652(a)(10) in § 425.610(a)(3);

++ Add reference to § 425.654(a) in § 425.611(c)(2)(i);

++ Add reference to § 425.652(a)(4) in § 425.611(c)(2)(ii)(A);

++ Add reference to § 425.654(a)(3) in § 425.611(c)(2)(ii)(B);

++ Within § 425.611(c)(2)(iii), remove the specific reference to 5 percent of national per capita FFS expenditures for assignable beneficiaries, to account for the proposed modifications to the cap on the regional adjustment as specified in section III.G.5.c.(5) of this proposed rule, and to add a reference to § 425.656(c)(3), which refers to the cap of 5 percent of the national per capita expenditure amount applied to positive regional adjustments, and the cap of 1.5 percent of the national per capita expenditure amount applied to negative regional adjustments for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years; and add a reference to § 425.652(a)(8)(iv) which refers to the cap equal to 5 percent of the national per capita expenditure amount that is applied in calculating the prior savings adjustment; and

++ Add references to § 425.652(a)(5)(ii) (referring to the national component of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3) and § 425.652(b)(2)(i) (referring to the national component of the blended growth rate used to update the benchmark) in § 425.611(c)(2)(v).

• Under subpart I, which governs the reconsideration review process, add a reference to § 425.652 in § 425.800(a)(4).

We also propose to correct the following inadvertent errors in cross-references:

• In § 425.601(f)(5)(ii), remove the reference ''paragraph (f)(4)(i) of this section'', and add in its place the reference ''paragraph (f)(5)(i) of this section''.

• In § 425.601(f)(5)(iv), remove the reference ''paragraphs (f)(1) and (2) of this section'', and add in its place the reference ''paragraphs (f)(1) through (3) of this section''.

Additionally, we believe it is appropriate to specify in the proposed new regulation at § 425.656(e) a narrower set of special rules for determining the weights used in calculating the regional adjustment for certain ACOs that previously participated in the Shared Savings Program. In the December 2018 final rule (83 FR 68024), we established § 425.601(e)(2)(ii) which specifies that for renewing or re-entering ACOs whose prior agreement period benchmark was calculated according to § 425.603(c), we consider the agreement period the ACO is entering upon renewal or re-entry in combination with either of the following in determining the weight used in the regional adjustment calculation in the ACO's new agreement period: (A) The weight previously applied to calculate the regional adjustment to the ACO's benchmark in the ACO's most recent prior agreement period; or (B) For new ACOs that are identified as re-entering ACOs, we consider the weight previously applied to calculate the regional adjustment to the benchmark for the ACO in which the majority of the new ACO's participants were participating previously. With the agreement period beginning on January 1, 2022, all ACOs continuing their participation in the Shared Savings Program that were previously under the benchmarking rebasing methodology specified in § 425.603 are now participating under the benchmarking methodology specified in § 425.601. However, it is possible that an ACO that participated in a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019, and whose rebased benchmark was established in accordance with § 425.603(c), and whose participation agreement expired without having been renewed, or whose participation agreement was terminated under § 425.218 or § 425.220, may seek to re-enter the Shared Savings Program. Therefore, we believe it is necessary to maintain special rules for determining the weights used in the regional adjustment calculation for re-entering ACOs. Accordingly, we propose to incorporate the policies that currently apply to re-entering ACOs under § 425.601(e)(2)(ii) in the new regulation at § 425.656(e).

Lastly, we propose to remove from the existing regulations on calculating county expenditures and regional expenditures an extraneous step in the calculation specified under § 425.601(d)(3). This provision specifies that CMS weights aggregate expenditure values determined for each population of beneficiaries according to Medicare enrollment type to reflect the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year. However, at no point in the calculation do we actually combine the risk adjusted regional expenditures across the four Medicare enrollment types to determine a single risk adjusted regional expenditure value. Risk adjusted regional expenditures are incorporated in all relevant calculations at the Medicare enrollment type level. Similarly, as part of our proposal to establish a new regulation at § 425.654 to govern the calculation of county expenditures and regional expenditures for agreement periods beginning on January 1, 2024, and in subsequent years, we would also omit this extraneous step in the calculation.

6. Reducing Undue Administrative Burden and Other Policy Refinements

a. Overview

We are dedicated to reducing unnecessary ACO and CMS administrative burden where possible. In response to requests from interested parties from prior rules, we are proposing 2 burden reduction proposals and 2 policy refinements in this proposed rule. If finalized in the CY 2023 PFS final rule, the policy proposals and refinements would be implemented January 1, 2023. Specifically, we propose the following, which are discussed in more detail in sections (b) through (e) below:

• Modify § 425.310 to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating notifications to beneficiaries and participants.

• Amend the beneficiary notification requirements at § 425.312 to reduce the frequency of certain beneficiary notifications from once annually to once in an agreement period, and to further clarify the settings in which ACO participants are expected to make required beneficiary notifications by displaying signs in their facilities.

• Streamline the SNF 3-Day Rule Waiver application review process by amending requirements at § 425.612(a)(1)(i)(A) to include an ACO attestation that plan narratives are in place and available to CMS upon request.

• Amend regulations at §§ 425.702(c)(2) and 425.704(b) to recognize ACOs structured as OHCAs for data sharing purposes.

We anticipate that, collectively, these proposals would significantly reduce administrative burden in the Shared Savings Program.

b. Proposal To Modify Marketing Material Review Requirements

(1) Background

The Shared Savings Program regulations define ''marketing materials and activities'' at § 425.20 to include, without limitation, ''general audience materials'' and activities used or conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers about the Shared Savings Program. General audience materials include brochures, advertisements, outreach events, letters to beneficiaries, web pages, data-sharing opt-out letters, mailings, and social media. The following beneficiary communications are not marketing materials and activities: certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health-related issues; educational information on specific medical conditions; written referrals for health care items and services; and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and § 164.508(a)(3)(i).

In addition, the Shared Savings Program regulations impose certain marketing requirements at § 425.310 regarding the content and approval of marketing materials and activities. Specifically, under § 425.310(c), all marketing materials and activities must: (1) use template language developed by CMS, if available; (2) not be used in a discriminatory manner or for discriminatory purposes; (3) comply with § 425.304 regarding beneficiary incentives; and (4) not be materially inaccurate or misleading. Under § 425.310(a), marketing materials may be used 5 business days following their submission to CMS if: (1) The ACO certifies compliance with all the marketing requirements under this section; and (2) CMS does not disapprove the marketing materials or activities. Under § 425.310(b), marketing materials and activities are deemed approved after the initial 5-day review period. In other words, if CMS has not disapproved of the marketing submission within 5 days, the ACO may use the submitted marketing materials. CMS may subsequently issue a written notice of disapproval at any time, including after the expiration of the initial 5-day review period, at which point the ACO must discontinue use of the disapproved marketing materials. Per § 425.310(d), failure of an ACO to comply with the marketing requirements will subject the ACO to pre-termination actions sets forth in § 425.216, termination from the program under § 425.218, or both.

As indicated in the November 2011 final rule (74 FR 67948), we finalized these marketing policies as an aspect of patient-centeredness, indicating that we believed it would be appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of ACO-related marketing activities and materials to ensure that such communications and marketing are used only for appropriate purposes, such as notification that a beneficiary's healthcare provider is participating in the ACO, issuance of any CMS-required notices, or notification of provider or ACO terminations. We indicated that we were sensitive to the operational burden imposed on ACOs by these marketing requirements, such as the ACO bearing sole responsibility for collecting and submitting to CMS all marketing materials in use by the ACO, ACO participants, and ACO providers/suppliers, and we noted our desire to balance this burden with the need for appropriate beneficiary protections.

Historically, the majority of marketing submissions for the Shared Savings Program are approved upon review or are found not to constitute marketing materials and activities, as defined at § 425.20. For example, in 2021, of 241 Shared Savings Program marketing material submissions reviewed by CMS, 163 (~68 percent) of those submissions were approved, while only 1 submission (0.4 percent) was denied. For the remaining 77 submissions (~32 percent), 58 submissions did not to meet the definition of marketing materials and activities; 9 were approved after the ACO responded with additional information or resubmitted revised materials; 9 were withdrawn for unspecified reasons, and 1 was neither approved nor denied and remained in non-compliant status.

We believe that marketing materials and activities are important communications between an ACO and its patients and participants, and we remain committed to patient-centered care, patient engagement, and program transparency in the Shared Savings Program. However, given the breakdown of marketing material review dispositions, the time and resources CMS currently expends to review all submitted marketing materials, and the additional effort for ACOs to submit these materials prior to use, we believe the current submission requirements create an unnecessary administrative burden for both CMS and ACOs that is not outweighed by the benefits of the current policy.

(2) Proposal To Modify Regulations on Review of ACO Marketing Materials

To reduce unnecessary administrative burden, we propose to remove the requirement at § 425.310(a) that ACOs submit marketing materials and activities to CMS before use, but would maintain the requirement that ACOs must provide marketing materials upon request. Additionally, we propose to remove the provisions in § 425.310(b) regarding deemed approval of marketing materials and activities after a 5-day review period. We note that ACOs must continue to comply with all Shared Savings Program regulations, including the marketing material content requirements that currently appear at § 425.310(c). Our proposed policy does not affect an ACO's obligation to comply with marketing content requirements, and we propose to retain the authority to request the submission of marketing materials and activities at any time. We propose that if we determine an ACO's marketing materials and activities to be non-compliant, we will issue a written notice of disapproval under proposed § 425.310(b)(1). In addition, we propose that ACOs must discontinue (and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue) use of any disapproved materials or activities. Under our proposal, we would retain language stating that the failure to comply with the requirements of § 425.310 will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

We believe that the existing marketing material content requirements and our proposed policy to review marketing materials and activities upon request would provide sufficient safeguards and

appropriate patient protections. Additionally, beneficiaries may express concerns regarding ACO marketing materials by utilizing the 1–800–MEDICARE hotline, contacting their healthcare provider, or submitting a complaint to the Medicare Ombudsman's office, while ACOs and other interested parties may use any of these avenues, as well as express concerns via the Shared Savings Program mailbox or via their ACO coordinators.

We would codify our proposal by revising § 425.310 to remove existing references to CMS' collection, review, and approval of marketing materials. Specifically, we propose to remove the marketing material file and use requirement at § 425.310(a) so that they may be used without prior approval. We propose that § 425.310(a) would set forth without change the marketing material content requirements that currently appear in paragraph (c) (for example, the requirement to use template language and not be materially inaccurate or misleading). We propose to revise paragraph (b) to remove language at § 425.310 (b)(1) regarding deemed approval after expiration of a 5-day review period and to retitle the section ''Monitoring.'' Under proposed paragraph (b)(1), CMS may request the submission of marketing materials and activities at any time, and if CMS determines that the marketing materials and activities do not comply with the content requirements of paragraph (a), CMS will issue written notice of disapproval to the ACO. Proposed paragraph (b)(2) sets forth without change language that currently appears § 425.310(b)(2)(ii) regarding the duty to cease use of disapproved marketing materials and activities. Finally, proposed paragraph (c) would set forth without change the sanctions provision that currently appears at § 425.310(d).

If finalized, our proposed modifications to § 425.310 would become effective on January 1, 2023. We believe that, if finalized, this proposal would reduce administrative burden for both CMS and for ACOs, while maintaining program integrity and beneficiary protections. We believe the revised regulation would provide sufficient safeguards and appropriate patient protections.

c. Proposal To Modify Beneficiary Notification Requirements

(1) Background

Under § 425.312(a), an ACO is required to ensure that Medicare FFS beneficiaries are notified of the following: (1) that each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program; (2) the beneficiary's opportunity to decline claims data sharing; and (3) the ability to, and process by which, the beneficiary may identify or change identification of a primary care provider for purposes of voluntary alignment.

Section 425.312(a)(2) sets forth the manner in which ACOs or ACO participants are required to notify beneficiaries of this information. ACO participants must post signs in their facilities and, in settings in which beneficiaries receive primary care services, make standardized written notices available upon request. In addition, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(ii)). Finally, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii)).

We periodically receive inquiries from ACOs seeking clarification as to the types of facilities in which signs are required to be posted. In addition, ACOs have continued to express concern regarding the obligation to provide an annual standardized notification prior to or at a beneficiary's first primary care service visit of the performance year. Specifically, ACOs state that such notices may confuse beneficiaries, who misinterpret the notice and believe that it signifies a change to their Medicare benefits or otherwise represents an undesirable or disadvantageous change regarding their health care services. ACOs assert that this confusion may cause a beneficiary to opt out of data sharing, which could result in less cohesive care, duplicative or unnecessary medical tests, or contraindicated prescription drug therapy. ACOs have reported that the information in the beneficiary information notice is unclear and that the frequency of notifications containing identical information is redundant. According to ACOs, the beneficiary notices also cause unnecessary administrative burden to ACOs because ACOs retain documentation that the notices were sent, and ACOs may be required to perform additional follow-up for patients contacting ACOs with questions regarding the notice.

CMS remains committed to program transparency. Beneficiary notices are important communication tools, and we believe that ACOs are in the best position to communicate with beneficiaries regarding their care and the purposes for Medicare claims data sharing. We want to ensure that beneficiaries understand the advantages of their participation in ACOs, that their data is secure, that only the minimum necessary data is collected, and how this data is used for purposes of improving the quality of care for beneficiaries in the Shared Savings Program. We are working to improve the beneficiary notice to ensure that the content of the notice utilizes plain language and is beneficiary-friendly, as well as affirming patient choice and clarifying the beneficiary's opportunity to decline claims data sharing.

(2) Proposal To Clarify Location of Beneficiary Notification Signage

ACOs and ACO participants frequently ask whether CMS requires signage to be posted in all facilities or only those where primary care services are provided. Although we believe the existing regulation text is clear on this point, we wish to provide clarification in this proposed rule that ACO participants are required to post beneficiary notification signs in all of their facilities, whether or not primary care services are provided in every facility. Accordingly, we propose to modify § 425.312(a)(2)(i) to move the requirement for standardized written notices available to the newly proposed, redesignated § 425.312(a)(2)(ii). With this modification, CMS clarifies that an ACO participant must post signs in ''all'' of its facilities and make standardized written notices available upon request in ''all'' settings in which beneficiaries receive primary care services. Signage notifies the entirety of a patient population that the facility participates in an ACO and is therefore qualitatively different from standardized written notices provided directly to individual patients in conjunction with primary care service visits. We note that the requirement to furnish standardized written notices upon the request of a beneficiary applies only in settings or facilities in which beneficiaries receive primary care services. We are not proposing to expand the care settings in which standardized written notices must be furnished to beneficiaries upon request.

(3) Proposal To Reduce the Frequency of Annual Standardized Written Notices

In addition to providing standardized written notices to beneficiaries upon

request, ACOs and ACO participants are currently required to furnish standardized written notices prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii), (iv)). We continue to believe that requiring periodic beneficiary notifications affords ACOs and ACO participants an opportunity for direct engagement with the beneficiary, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. The requirement promotes program transparency and empowers patients with the knowledge of the ACO's mission, data sharing requirements, and ACO operations, thereby allowing patients to make informed decisions about where they receive care. Therefore, we intend to retain the beneficiary notification policies, but in the interest of an overall reduction in administrative burden, we propose to modify § 425.312(a) to reduce the frequency with which an ACO or ACO participant must furnish standardized written notifications to beneficiaries from up to 5 times per agreement period to once per agreement period. We also propose to implement a new follow-up beneficiary communication that we expect will reduce beneficiary confusion and improve beneficiary comprehension. Our proposed changes would become effective January 1, 2023.

First, we propose to revise the requirements regarding annual beneficiary notifications, which currently appear at § 425.312(a)(2)(ii) and (iii). Specifically, at proposed § 425.312(a)(2)(iii), we propose to provide that, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary with a standardized written notice at least once during an agreement period. Similarly, at proposed § 425.312(a)(2)(iv), we propose to provide that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period. In either case, the standardized written notice must be furnished prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant, and the notice must be in the form and manner specified by CMS.

Second, in the interest of ensuring program transparency, maintaining beneficiary protections, reducing beneficiary confusion, and improving beneficiary comprehension, we propose at § 425.312(a)(2)(v) to require the ACO or ACO participant to follow up with each beneficiary to whom it furnished the standardized written notice pursuant to proposed § 425.312(a)(2)(iii) or (iv). We propose that the follow-up communication may be verbal or written and must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the first standardized written notice was provided. The follow up communication must afford the beneficiary an additional opportunity to ask any outstanding questions they may have, thereby reducing any potential beneficiary confusion and improving their understanding of the advantages of value-based care. The follow-up communication may be provided in any manner, so long as the form of the follow up communication includes a meaningful opportunity for beneficiaries to ask questions and engage with a representative of the ACO or ACO participant with regard to the beneficiary notice. Because of the flexibility granted to ACOs in communicating key features of the beneficiary notification, we propose that ACOs track and document how this beneficiary communication is implemented and make this documentation available to CMS upon request.

ACOs should administer the communication in the way that best suits their beneficiary population. We believe that while the follow-up communication would be most effective when occurring during a primary care service visit, it may be delivered in another manner. We note that while it is permissible to provide the standardized written notice again during the course of the follow-up communication, simply providing the same standardized written notice as the full extent of the follow-up communication is not sufficient to satisfy the proposed requirements at 425.412(a)(v), since doing so would not allow for an opportunity to engage the beneficiary and ensure they have the chance to ask any questions they may have as a result of receiving the standardized written notice. The implementation of the follow-up communication does not create a new benefit or billable service and therefore, no additional payment will be made for the follow-up communication.

We are actively engaged in efforts to improve beneficiary notification materials, which include gathering feedback from beneficiaries and beneficiary representatives to make improvements as to how we disseminate information to beneficiaries. Further, we will work expeditiously to provide any updated and new materials as they become available. Although our proposal will reduce the frequency with which beneficiaries will receive the information that appears in standardized written notices, we note that this information is also readily available via signage in ACO facilities, as well as in the Medicare & You handbook. Additionally, we will maintain the requirement for ACO participants to make the notice available upon request in all settings in which beneficiaries receive primary care services. We note that ACOs and ACO participants may choose to provide the standardized written notice or follow-up beneficiary engagement communications more frequently than once per agreement period, and we would support their efforts to do so.

We seek comment on the proposed frequency of the notification and whether our proposal will reduce net burden and mitigate any potential beneficiary confusion.

d. Streamline SNF 3-Day Rule Waiver Application Review Process

Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient skilled nursing facility (SNF) care (the SNF 3-day rule). Section 1819(a) of the Act defines a SNF, in part, as an institution (or a distinct part of an institution) that is not primarily for the care and treatment of mental diseases but is primarily engaged in providing the following to residents: skilled nursing care and related services for residents who require medical or nursing care; or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The Medicare SNF benefit applies to beneficiaries who require a short-term intensive stay in a skilled nursing facility or rehabilitation facility, or both.

In the CY 2015 Shared Savings Program final rule (80 FR 32692), CMS used its authority under section 1899(f) to waive the SNF 3-day rule under section 1861(i) of the Act in order to carry out the provisions of section 1899 of the Act by offering ACOs that have accepted two-sided risk under the Shared Savings Program more flexibility under FFS Medicare to provide appropriate care for beneficiaries in the most appropriate care setting. CMS believes this is an opportunity to provide experienced, risk-bearing ACOs

with additional flexibilities to increase quality and decrease costs.

The waiver is codified in the Shared Savings Program regulations at § 425.612(a)(1). Specifically, for PY 2017 and subsequent performance years, CMS waives the SNF 3-day rule for eligible beneficiaries that are assigned to an ACO participating in a two-sided model (or as provided in § 425.612(a)(1)(iv) during a grace period for beneficiaries excluded from prospective assignment to such an ACO) and who receive covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO (a ''SNF Affiliate''). An ACO is eligible to use the SNF 3-Day Rule Waiver if the ACO participates in performance-based risk (for example, Levels C, D, or E of the BASIC track or the ENHANCED track) and has a SNF affiliate list. All other statutory and regulatory provisions regarding Medicare Part A post-hospital extended care services continue to apply.

An eligible ACO may apply for a programmatic waiver of the SNF 3-day rule to allow its assigned beneficiaries to receive coverage for inpatient SNF care without a prior 3-day inpatient hospital stay when admitted to a SNF affiliate. A SNF affiliate is a SNF that has executed a written agreement with an eligible ACO that meets the requirements of § 425.612(a)(1)(iii)(B) and is included on the ACO's SNF affiliate list. If the SNF affiliate is eligible to be included in the CMS 5-star Quality Rating System, it must have and maintain an overall rating of 3 or higher (§ 425.612(a)(1)(iii)(A)).

It is important to note that the Shared Savings Program SNF 3-Day Rule Waiver does not create a new benefit or extend Medicare SNF coverage to patients who could be treated in outpatient settings or who require long-term custodial care. Also, the SNF 3-Day Rule Waiver does not restrict a beneficiary's choice of provider or supplier. A beneficiary will continue to have the option to seek care from any Medicare FFS provider or supplier, including from a SNF or other facility that is not an affiliate of an ACO participating in the Shared Savings Program. If a beneficiary that is assigned to an ACO chooses to receive care from a SNF or other facility that is not an affiliate of the ACO, normal Medicare requirements apply, including the requirement for a 3-day inpatient hospitalization. The SNF 3-Day Rule Waiver is intended to provide ACOs that are participating in certain performance-based risk tracks with additional flexibility to increase quality and decrease costs.

(1) SNF 3-Day Rule Waiver Application Process

An ACO participating or applying to participate in performance-based risk within the BASIC track under § 425.605 or the ENHANCED track under § 425.610 may request to use the SNF 3-Day Rule Waiver at the time of application to participate in the program or during its agreement period. The waiver request must be submitted in a form and manner and by a deadline specified by CMS, which typically occurs once each year. Any ACO, including those applying for the waiver during the term of an existing participation agreement, must apply during the annual application process. Current regulations require that an ACO submit an application demonstrating that it has the capacity to identify and manage beneficiaries who would either be directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. Under § 425.612(a)(1)(i), to be eligible to use the SNF 3-Day Rule Waiver, an ACO must submit supplemental application materials that include, but are not limited to, a list of SNFs with whom the ACO will partner (that is, a SNF affiliate list), along with executed written SNF affiliate agreements between the ACO and each listed SNF, in addition to 3 narratives describing how the ACO plans to implement the waiver. The narratives must include: the communication plan between the ACO and its SNF affiliates, a care management plan for beneficiaries admitted to a SNF affiliate, and a beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes.

Historically, the SNF 3-Day Rule Waiver originated from the CMS Innovation Center's Pioneer ACO and Next Generation ACO Models. These models included application questions (answered by the ACO in a narrative format) which, while not codified in regulation, were transformed into plan narrative requirements in the Shared Savings Program SNF 3-Day Rule Waiver application. In the CY 2015 Shared Savings Program final rule (80 FR at 32805), we discussed a variety of issues that could be addressed in these narratives, such as the protocol that will be followed by ACOs for evaluating and approving admissions to a SNF under the waiver and consistent with the beneficiary eligibility requirements and the education and training for eligible SNFs regarding waiver requirements. We have not set forth specific ways that ACOs must address issues in their plan narratives because we believe the ACO is in the best position to establish its protocols, develop SNF training, and otherwise determine how to best coordinate care for patients transferred to their SNF affiliates.

After successfully implementing the Shared Savings Program SNF 3-Day Rule Waiver for several performance years, we determined in 2017 that some application requirements were burdensome for both CMS and ACOs, did not add value to the application review, or were not permitted by regulation. For example, the SNF 3-Day Rule Waiver application originally included a narrative describing any financial relationships between an ACO, SNF affiliate and acute care hospital. Because the Shared Savings Program regulations do not prohibit ACOs or SNFs from having financial arrangements with acute care hospitals, nor do they require such arrangements, we discontinued the submission of this narrative. Previously, ACOs also submitted documentation for each proposed SNF affiliate demonstrating they met minimum star rating requirements. Because CMS could obtain the required star rating information directly from the CMS Care Compare website, this application submission requirement was discontinued. We removed the requirement for these two application elements in the CY 2018 PFS final rule (82 FR 52976).

At the time of these modifications, CMS chose to retain the three narratives related to an ACO's communication plan, care management plan, and beneficiary evaluation and admission plan without establishing specific criteria for an ACO's process for implementing the SNF 3-Day Rule Waiver. We have since found that these plan narratives have not aided in our ability to evaluate an ACO's capacity to identify and manage beneficiaries who may be admitted to a SNF affiliate beyond what is otherwise established within the application. These narratives describe the plans that exist and that the ACO will adhere to requirements for beneficiary eligibility set forth in the waiver, but the program continues to provide operational flexibility to ACOs to develop their own internal processes and protocols.

(2) Proposal To Modify the CMS Review Process for ACOs Applying for a Shared Savings Program SNF 3-Day Rule Waiver

We remain committed to reducing unnecessary application and/or program burden where possible and consider application attestations as a way of streamlining processes when appropriate. The submission of the three remaining narratives has largely functioned as a mechanism for ACOs to confirm they have established operations for communicating between the ACO and its SNF affiliates, establishing a care management plan, and beneficiary evaluation and admission plan. The existence of the three narrative plans provides some assurance of an ACO's capacity to identify and manage beneficiaries who may be admitted to a SNF affiliate. However, as a payer, we do not have the experience that would be required to evaluate the appropriateness of the contents of these plans. Therefore, to reduce CMS burden, we propose to remove the requirement to submit the plan narratives and instead propose to require ACOs to certify that they have a communication plan, care management plan, and beneficiary evaluation and admission plan in place prior to SNF 3-Day Rule Waiver approval. Such plans should continue to address the issues we previously discussed in the CY 2015 Shared Savings Program final rule at 80 FR 32805. ACOs must continue to develop robust processes to implement the 3-Day Rule Waiver and to successfully transition care for their identified FFS beneficiaries and must be able to provide upon request a narrative describing their communication plan, care management plan, and beneficiary evaluation and admission plan. If our proposed policy is finalized, an ACO would be subject to compliance action if it fails to submit, upon CMS request, the narratives about its capacity to manage patients under the waiver. The proposed attestation requirement retains oversight for ensuring that an ACO has the capacity to identify and manage beneficiaries while reducing burden during the application process.

Furthermore, we have determined that other provisions of our regulations provide sufficient safeguards to ensure that CMS can assess an ACO's capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient stay of less than 3 days. We have found that these experienced, risk-bearing ACOs focus on care coordination and clinically-integrated, patient-centered care. Such investments in care coordination not only improve patient outcomes, but also serve to reduce the cost of care. In addition, our ongoing oversight and program compliance monitoring of the use of the waiver by ACOs helps us to ensure that ACOs have the capacity to identify and manage beneficiaries who are admitted to a SNF under the SNF 3-Day Rule Waiver.

In summary, we propose to amend § 425.612(a)(1)(i)(A) to require that an ACO applying to use the SNF 3-Day Rule Waiver must submit an attestation that it has established plan narratives (communication plan, care management plan, and beneficiary evaluation and admission plan) and will make them available to CMS upon request. We are making minor revisions to the narrative language by replacing ''the communication plan'' with ''a communication plan'' in § 425.612(a)(1)(i)(A)(*1*). We expect that, when implemented, our proposal will reduce the application review burden on CMS, as well as the burden on ACOs to submit this information.

e. Updating Shared Savings Program Data Sharing Regulations To Recognize ACOs Structured as Organized Health Care Arrangements (OHCAs) for Data Sharing Purposes

In the CY 2022 PFS final rule (86 FR 65261), we stated that we were considering whether it would be appropriate to revise the regulations at §§ 425.702(c) and 425.704(b) to allow data sharing with a Shared Savings Program ACO that has structured its relationship with its ACO participants as an OHCA, as that term is defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 CFR 160.103. This was in response to commenters who shared concerns about collecting patient-level all-payer data (eCQMs/MIPS CQM) from patients who were not assigned to the ACO. These commenters cited HIPAA and patient consent concerns related to sharing non-Medicare patient information with the ACO and with CMS for a population that is not assigned to the ACO and indicated that obtaining this consent would be an additional burden.

As we explained in the CY 2022 PFS final rule (86 FR 65261), we believe the disclosure of this all-payer data to CMS as required by § 414.1340(a) is permitted by the HIPCAA Privacy rule under the provision that permits disclosures of protected health information (PHI) as ''required by law.'' [276] We also encouraged ACOs and their ACO participants to consult with their legal counsel as necessary to ensure that their business associate agreements (BAAs) address the need to share data for patients covered by all payers with the ACO to permit the ACO to comply with its legal obligation to completely and accurately report this data to CMS. Nevertheless, these comments prompted us to consider whether the current Shared Savings Program regulations provide sufficient flexibility regarding different arrangements permitted under HIPAA. In the CY 2022 PFS final rule, we stated that we were specifically considering potential revisions to the regulations at §§ 425.702(c) and 425.704(b) to permit data sharing with an ACO structured as an OHCA. We are now proposing those changes as part of this proposed rule.

In the April 2011 proposed rule (76 FR 19528, 19556), we discussed the importance of data sharing and beneficiary protections in light of existing HIPAA requirements. We noted that ACO participants and ACO providers/suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. We also stated that an ACO may itself be a HIPAA covered entity if it is a health care provider that conducts such transactions or may qualify as the business associate of its covered entity ACO participants and ACO providers/suppliers based on the quality assessment and improvement activities that the ACO is conducting on behalf of those ACO participants and ACO providers/suppliers (76 FR 19556). In the November 2011 final rule (76 FR 67846 through 67851), we established requirements for data sharing with ACOs that are designed around the HIPAA provisions for ''health care operations'' disclosures. These provisions permit CMS to disclose PHI without obtaining individual authorization for the health care operations activities of the recipient of the data (that is, the ACO).[277] As we explained in the CY 2015 PFS final rule (80 FR 32692), ACOs work with their ACO participants and ACO providers/suppliers to evaluate their performance, conduct quality assessment and improvement activities, perform care coordination activities, and conduct population-based activities relating to improved health for their assigned beneficiary population. When done by

[276] 45 CFR 164.512(a).

[277] 45 CFR 164.506(c)(4).

or on behalf of a covered entity, these are activities that would qualify as health care operations under the first and second paragraphs of the definition of ''health care operations'' at 45 CFR 164.501 (76 FR 19558). Therefore, in the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b), we have focused on ACOs that are themselves HIPAA-covered entities, or that are acting as business associates on behalf of their ACO participants and ACO providers/suppliers who are HIPAA-covered entities.

We believe that most ACOs are acting as business associates of their covered entity ACO participants (the providers and suppliers that are part of the ACO). However, we believe it is possible that some ACOs may choose to operate as an OHCA.

An OHCA is another type of entity that is recognized under the HIPAA regulations. An OHCA is a distinct entity from a covered entity or a business associate under HIPAA, although it is made up of covered entities. As most relevant to Shared Savings Program ACOs, under 45 CFR 160.103, an OHCA is defined to include an organized system of health care in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participate in specified joint activities such as quality assessment and improvement activities and payment activities.[278] In addition, the purpose of the OHCA is that participants in such clinically integrated settings are able to share health information freely not only for purposes of care, but also to improve their joint operations (65 FR 82494). The HIPAA Privacy Rule has specific provisions relevant to OHCAs. For example, under 45 CFR 164.506(c)(5), a covered entity that participates in an OHCA may disclose PHI about an individual to other participants in the OHCA for any health care operations activities of the OHCA.

We note that the Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology (ONC) have recognized in joint guidance that ACOs may operate as OHCAs.[279] An ACO that operates as an OHCA would be able to share PHI among the covered entities in the OHCA without getting authorization from individuals for the health care operations of the OHCA and would be permitted to share PHI for the health care activities of the OHCA without entering into BAAs with each other.[280]

Effective for performance year 2023 and subsequent performance years, we propose to modify the Shared Savings Program data sharing regulations at §§ 425.702(c)(2) and 425.704(b) to specify that ACOs acting as OHCAs may request aggregate reports and beneficiary-identifiable claims data from CMS, respectively. As outlined above, these proposed changes would recognize an OHCA as an additional organizational structure under which an ACO can request data from CMS. Our intention is to update the data sharing regulations to reflect how ACOs may be structured and provide flexibility with respect to the different arrangements permitted under HIPAA for purposes of data sharing.

Separately, we believe that an OHCA structure potentially could address some of the concerns that commenters have raised about ACOs collecting and reporting all-payer data to CMS as required under the APP. However, we note that our proposal is limited to the Shared Savings Program regulations governing CMS' data sharing with ACOs and is not intended to affect or modify any existing obligations under the HIPAA Privacy Rule. It is the ACOs' responsibility to consult with their legal counsel and others as necessary to determine how to structure their arrangements with their ACO participants and ACO providers/suppliers to comply with HIPAA requirements.

7. Seeking Comment on Incorporating an Administrative Benchmarking Approach Into the Shared Savings Program

a. Background on Longer Term Approach to Benchmarking Under the Shared Savings Program

We have set a goal that 100 percent of Original Medicare beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.[281] Achieving this goal will require significant growth in the number of ACOs participating in the Shared Savings Program, or the number of beneficiaries served by existing ACOs, or both. Benchmarks are a core policy instrument for providing sufficient incentives for ACOs to enter and remain in the Shared Savings Program, with significant implications on impacts to the Medicare Trust Funds.

The benchmark is a cost target used to determine savings or losses for an ACO compared to performance year expenditures for its assigned beneficiary population and, importantly, to create incentives for ACOs to reduce spending and generate savings, which will be shared by the ACO and CMS; by extension, these savings opportunities also create incentives for providers and suppliers to participate in ACOs. Many factors need to be considered in establishing benchmarks including the variability in the composition of ACOs, the beneficiary populations they serve, and their experience with accountable care models, as well as the need to protect the Trust Funds and minimize unintended consequences such as market consolidation and patient risk selection. In this section of this proposed rule, we describe and seek comment on a modified benchmarking methodology which may boost participation, increase savings to the Medicare Trust Fund and make long-term participation in the Shared Savings Program possible for more ACOs.

Currently, we establish, adjust, update and reset the historical benchmark under the Shared Savings Program in accordance with § 425.601. An ACO's benchmark is established based on historical expenditures for a population of beneficiaries that would have been assigned to that ACO in the 3 years prior to the start of its agreement period. In establishing the benchmark, we adjust the benchmark based on the ACO's spending relative to its service area (referred to as the regional adjustment). For each performance year of the ACO's 5-year agreement period, we risk adjust the benchmark for changes in severity and case mix of the ACO's assigned beneficiaries, and we update the benchmark using growth rates that are a blend of observed national and regional FFS spending trends. We reset (or rebase) the ACO's benchmark at the start of the ACO's second and each subsequent agreement period. Refer to section III.G.5. of this proposed rule for a more detailed description of the statutory and regulatory background of the Shared Savings Program's current benchmarking methodology and certain benchmark calculations, as well as proposed modifications to the current

[278] For the complete definition of an OHCA, see 45 CFR 160.103.

[279] Permitted Uses and Disclosures: Exchange for Health Care Operations (*https://www.healthit.gov/sites/default/files/exchange_health_care_ops.pdf*).

[280] Please see HIPAA For Professionals FAQ 242 (Are covered entities that engage in joint activities under an organized health care arrangement (OHCA) required to have business associate contracts with each other?) (*https://www.hhs.gov/hipaa/for-professionals/faq/242/may-i-share-protected-health-information-directly-with-another/index.html*).

[281] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. *Health Affairs.* January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

benchmarking methodology for agreement periods starting on January 1, 2024, and in subsequent years.

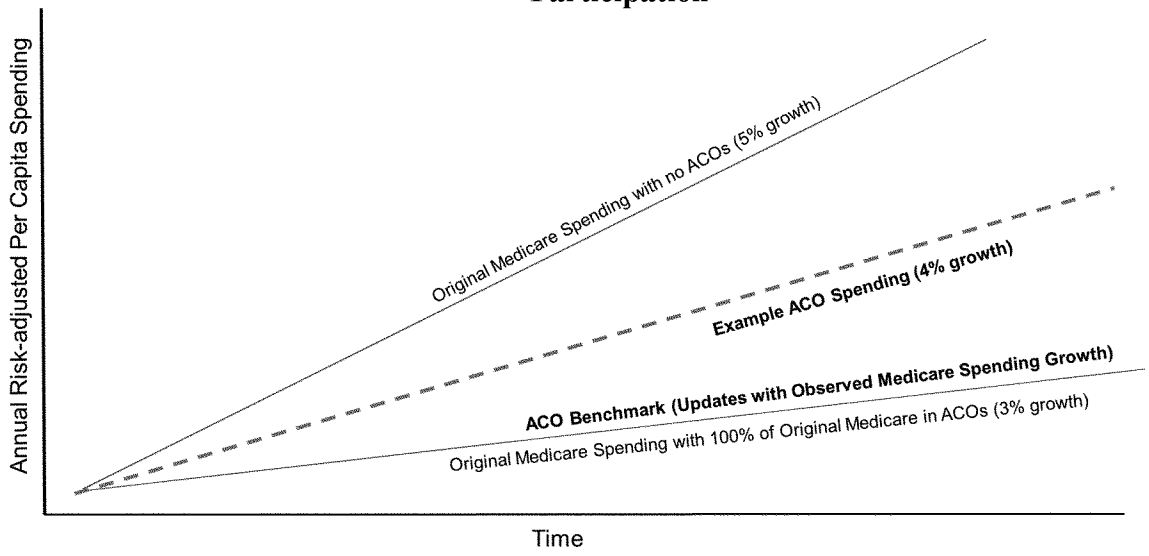
ACOs and other interested parties have expressed concerns about the effects of current benchmarking methods on ACOs' incentives to generate savings, the extent to which they are able to share in those savings, and thus the incentives for ACOs to enter and remain in the program over the long-term. Specifically, there are two ways in which the use of factors based on realized FFS spending (which reflects any ACO spending reductions) can lead to lower benchmarks, which we will refer to as ''ratchet'' effects: (1) downward pressure on an individual ACO's benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs.

The first type of ratchet effect occurs at the individual ACO level, when an ACO's own savings reduce its benchmark, which can occur when we reset the historical benchmark at the start of the ACO's second or subsequent agreement period. When the benchmark years correspond to performance years from the ACO's preceding agreement period, the benchmark reflects a portion of any spending reductions achieved by the ACO. A ratchet effect can also occur through the use of factors based on the regional FFS expenditures to adjust the benchmark and update an ACO's benchmark; specifically, when an ACO reduces spending, it also reduces average spending in its region, thereby lowering the regional adjustment to its benchmark. This effect becomes more prominent as an ACO has increasing market share in its region. Critically, ACOs must be able to retain the ability to achieve savings over the long-term to have an incentive to take the steps necessary to generate them, as there are costs associated with delivering care outside of the fee-for-service construct and in running an ACO to lower (and maintain) reduced spending levels.

The second type of ratchet effect occurs at the program level, where overall program success can apply downward pressure on ACOs' benchmarks through the method for updating benchmarks each performance year for changes in expenditures between Base Year 3 (BY3) and the performance year. We determine the update factor retrospectively using a blend of realized national and regional FFS expenditure growth rates, which incorporates the collective impact of ACOs on spending across Original Medicare. As a greater portion of Medicare FFS beneficiaries are assigned to ACOs, this program level ratcheting effect increasingly diminishes incentives to participate in the Shared Savings Program. If all beneficiaries enrolled in the Original Medicare FFS program under Parts A and B were assigned to an ACO, calculating the update factor based on realized spending growth rates would necessitate that some ACOs would experience expenditure growth in excess of the update factor (and forgo shared savings), even if all ACOs reduced spending growth. That is, an ACO would have to reduce spending more than the average ACO in order to earn savings, all else equal (absent regional adjustments to historical benchmarks). Similarly, program-wide savings lower the average per capita amounts of expenditures for an ACO's regional service area which are used in computing the regional adjustment to the historical benchmark. As ACOs' benchmarks converge toward average realized FFS spending, approximately half of ACOs will necessarily be given benchmarks below their spending at the start of their current agreement period, even if all ACOs have generated spending reductions relative to the counterfactual (that is, what spending would have been without the ACO). This downward pressure of program success on benchmark updates means that ACOs collectively keep less of the savings they generate. In the context of CMS' strategic objective to increase the number of Medicare beneficiaries in a care relationship with quality and total cost of care accountability, we anticipate that this program level ratcheting effect will become more pronounced with the growth in the number of beneficiaries assigned to ACOs, further weakening incentives to participate in the Shared Savings Program with the potential for impeding progress towards the fulfillment of this same goal.

For illustrative purposes, consider a scenario in which all Original Medicare beneficiaries are receiving the plurality of their primary care from an ACO provider/supplier, and thus are assigned to an ACO. Assume that FFS expenditure growth in the absence of ACOs would be 5 percent each year, but that ACOs, on average, slow expenditure growth to 3 percent each year. Under the current benchmarking approach, the update factor applied to an ACO's benchmark would be 3 percent, matching the average overall FFS expenditure growth rate under 100 percent ACO penetration. However, because 3 percent is the average growth rate, there will be ACOs with both higher and lower growth rates than 3 percent, meaning that some ACOs' growth in expenditures will outpace their benchmarks, even if they reduced spending relative to the counterfactual. In this example, an ACO that limited expenditure growth to 4 percent would (ignoring regional adjustments to the benchmark) show losses, despite reducing spending relative to the 5 percent growth rate expected without ACOs. Figure 2 provides a visual example of this scenario. provides a visual example of this scenario.

FIGURE 2: Illustrative Example of ACO Benchmarking and Spending Compared to Medicare Spending Growth With 100% ACO Participation and Without ACO Participation



MedPAC and researchers are also examining the Shared Savings Program benchmarking methodology and have noted many of the above concerns. MedPAC has discussed ratchet effects in ACO benchmarks in its November 2021 public meeting [282] and January 2022 public meeting,[283] with the general consensus that eliminating ratcheting effects is essential for the long-term sustainability of the Shared Savings Program. Many of the commissioners discussed a longer-term approach under which CMS would update ACOs' benchmarks annually using ''exogenous'' factors, meaning factors not impacted by the individual or collective performance of ACOs. Under this approach, which has also been referred to as administratively set benchmarks, benchmarks may be set prospectively based on projected growth in volume and intensity of FFS services, with guardrails in place to account for actual changes in FFS prices, demographics, and large projection errors. McWilliams, Chen, and Chernew have also raised concerns about ACO benchmark ratchet effects in outlining a blueprint for ACO benchmark changes in a recent white paper.[284]

Addressing these ratchet effects may also improve the experience of beneficiaries assigned to ACOs. ACOs are incentivized through sharing savings to provide services to beneficiaries that may not have been traditionally reimbursed under Medicare FFS. However, because any costs incurred in providing such services are not reflected in observed FFS spending but may help to reduce that spending and thus result in the ratcheting down of future benchmarks, incentives to provide such services are diminished. We anticipate that addressing these ratchet effects under the current benchmarking methodology will allow ACOs and their ACO participants to provide additional services and therefore improve the beneficiary experience in ACOs.

We have used a variety of approaches to mitigate the effect of ACO performance on their historical benchmarks, as described in earlier rulemaking and as summarized in section III.G.5. of this proposed rule, including: adjusting the ACO's rebased benchmark to account for savings generated by the ACO in its prior agreement period (§ 425.603(b)(2), June 2015 final rule, 80 FR 32788 through 32791); subsequently replacing the prior savings adjustment with an approach that incorporated factors based on regional FFS expenditures in resetting the ACO's benchmark through a regional adjustment (§ 425.603(c) through (f), June 2016 final rule, 81 FR 37953 through 37991); in addition, more recent modifications to use blended national-regional growth factors to trend and update the ACO's historical benchmark help ameliorate the ACO-specific ratchet effect caused by the use of regional trends to update benchmarks in areas where ACOs contribute substantially to regional trends (§ 425.601(a)(5), (b), December 2018 final rule, 83 FR 68005 through 68030).

In particular, the regional adjustment has reduced the impact of rebasing by partially decoupling an ACO's benchmark from its prior savings performance. Importantly, this adjustment also begins to converge benchmarks toward a consistent basis within a region, which we believe is an important objective for creating equitable payment within a market that rewards ACOs for relative efficiency. However, recent experience suggests that the regional adjustment may have led to selective participation, with 80–87 percent of ACOs subject to a regional adjustment having spending below their region for performance years 2017 through 2020, as shown in Table 68.[285]

[282] *https://www.medpac.gov/wp-content/uploads/2021/09/aco-benchmarks-medpac-nov-2021.pdf*; *https://www.medpac.gov/wp-content/uploads/2021/11/november21_medpac_transcript_sec.pdf.*

[283] *https://www.medpac.gov/wp-content/uploads/2021/10/APM-MedPAC-Jan22.pdf*; *https://www.medpac.gov/wp-content/uploads/2021/10/Jan22_MedPAC_Meeting_Transcript_SEC.pdf.*

[284] *https://www.brookings.edu/research/from-vision-to-design-in-advancing-medicare-payment-reform-a-blueprint-for-population-based-payments/.*

[285] *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.*

TABLE 68: Regional Adjustments to Benchmarks, All ACOs Subject to Regional Adjustment

All ACOs Subject to Regional Adjustment				
PY	Number of ACOs Subject to Regional Adjustment	Number of ACOs with Positive Regional Adjustment	Number of ACOs with Negative Regional Adjustment	Percent of ACOs with Positive Regional Adjustment
2017	73	59	14	80.8%
2018	136	113	23	83.1%
2019	133	107	26	80.5%
2019A*	205	178	27	86.8%
2020	412	357	55	86.7%

* PY2019A refers to the 6-month performance year from July 1, 2019, to December 31, 2019.

Furthermore, as shown in Table 69, selective participation effects are stronger for ACOs subject to downside risk, with 92–100 percent of ACOs having positive regional adjustments. This suggests that as ACOs are required to participate under performance-based risk and higher levels of downside risk, these selective participation effects may continue to grow. Setting aside the net costs to the Trust Funds from subsidizing participation by ACOs with spending already below their region, the chief concern with this pattern of participation under the current methodology is that the providers/suppliers with the greatest savings potential (those with high spending relative to their region) have fewer incentives to participate.

TABLE 69: Regional Adjustments to Benchmarks, ACOs in Two-sided Risk with Regional Adjustment

Two-sided Risk ACOs & Regional Adjustment				
PY	Number of ACOs Subject to Regional Adjustment	Number of ACOs with Positive Regional Adjustment	Number of ACOs with Negative Regional Adjustment	Percent of ACOs with Positive Regional Adjustment
2017	6	6	0	100.0%
2018	25	24	1	96.0%
2019	26	24	2	92.3%
2019A	97	93	4	95.9%
2020	176	168	8	95.5%

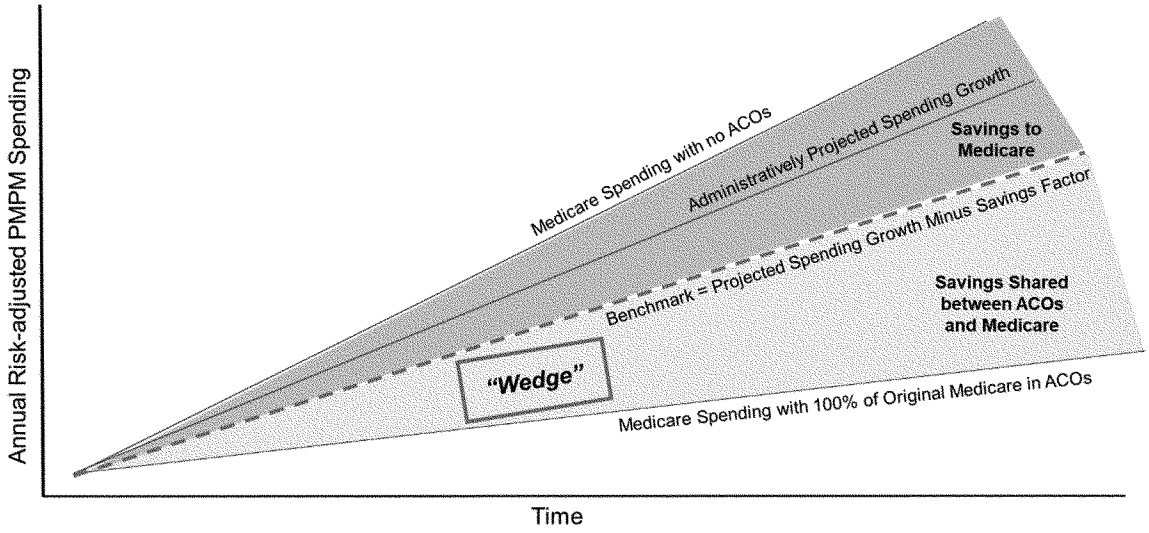
Through the benchmarking changes proposed in section III.G.5. of this proposed rule, we seek to more immediately address certain ratchet effects and features within the existing benchmarking methodology that result in selective participation. Specifically, the proposals to incorporate a prior savings adjustment, mitigate the impact of the negative regional adjustment, and to modify the benchmark update to incorporate a prospective, external factor (ACPT) are intended to address these dynamics. In this RFI, we seek comment on broader changes to the benchmarking methodology that may be needed to further strengthen incentives for providers and suppliers to participate in the Shared Savings Program and generate savings while preserving a mechanism for convergence to a consistent regional benchmarking approach that does not elicit selective participation.

b. Administratively-Established Benchmarks as a Potential Solution To Address Benchmarking Concerns

In this section, we describe and seek comment on a direction for future benchmarking that is designed to create a sustainable pathway for long term program savings for both ACOs and CMS and to address interested parties' concerns around ratcheting. Within this section, we provide an overview of and discuss details of key components of this approach.

This approach involves separating benchmarking update factors from realized FFS expenditure growth through the implementation of a prospective, administratively set annual growth rate to update benchmarks. Under this approach, benchmarks would be allowed to rise above realized FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to participate and achieve savings. Over time, use of this administratively set growth rate would allow for a wedge to accrue between average benchmarks and realized spending reductions, offering greater and more sustainable savings opportunities over the long-term for both Medicare and ACOs. Importantly, average benchmark growth would only exceed realized FFS spending growth to the extent that ACOs reduce spending, such that benchmarks remain at or below FFS spending levels projected in the absence of ACO participation. A graphic depiction of administratively-established benchmarking is provided in Figure 3.

FIGURE 3: Illustrative Example of Administratively-Established Benchmarking Approach



In concert with shifting from a benchmark update based on observed, or realized, FFS expenditure growth to a prospectively set trend that does not ratchet benchmarks downward as ACOs slow observed FFS expenditure growth, we are considering approaches that would minimize rebasing effects between agreement periods.

An administratively set benchmarking approach also offers a path for converging benchmarks gradually towards a common risk-adjusted rate in each region, which we anticipate would mitigate selective participation and improve the savings potential of the program. Allowing benchmarks to remain above observed FFS spending as ACOs lower spending also allows convergence of benchmarks to a regional rate that is above average regional FFS spending. Accordingly, convergence would not require ACOs operating in the same region to outcompete each other to accrue savings and should not discourage participation by ACOs with above average observed spending to the same extent that they are discouraged under the present methodology. As long as ACOs are generating savings collectively, this approach would allow all ACOs a chance to earn shared savings while reducing overall spending relative to projections and protecting the Trust Funds. In addition, benchmarks that exceed FFS spending would give ACOs flexibility to meet beneficiary needs through alternative modes of care such as virtual care or care management programs that have not traditionally been reimbursed under FFS.

Through the design of this approach, we believe CMS could address the selective participation effects that currently discourage participation by ACOs with higher spending compared to their regional services area. For example, we are considering an approach that would remove the negative regional adjustment to ACO historical benchmarks. This approach would mean that an ACO with spending above its regional average would receive a historical benchmark set at the ACO's average historical FFS expenditures, rather than below its historical spending levels due to the negative regional adjustment.

Ultimately, we envision such an approach would generate sufficient spending reductions for higher spending providers and suppliers such that CMS could consider a further modified benchmarking methodology under which ACOs' benchmarks would be calculated using a regionally consistent baseline. This longer-term option is discussed in section III.G.7.d. of this proposed rule. To maintain the divergence between benchmarks and realized FFS expenditures, regional baselines would be set to incorporate accrued FFS expenditure reductions relative to projected growth, rather than setting regional baselines at average FFS spending, which would effectively claw back the accrued savings. We consider regionally consistent benchmarks to be an important objective for the longer-term sustainability of the Shared Savings Program in that it would create equitable payment within a market by rewarding ACOs for their relative efficiency. Such an approach could also reduce complexity relative to both the current methodology (including the proposed changes described in section III.G.5. of this proposed rule) and the administratively established benchmark methodology used to generate convergence.

We invite comments on these concepts and on the design of an administratively established benchmarking methodology. In the remaining discussion in this section of this proposed rule, we provide additional details on the key features of an administrative benchmarking concept to inform commenters' consideration of this approach, including the administratively established update and discount factors, the continued use of certain factors in establishing and adjusting an ACO's historical benchmark, the convergence to a regional benchmark, and considerations for the post-convergence phase. We also welcome comments on the stages for implementing such an approach within the Shared Savings Program, particularly on an initial convergence phase and a post-convergence phase, and any other considerations related to this approach that we have not addressed in this proposed rule. We note that any such modifications to the benchmarking methodology would need to be adopted through notice and comment rulemaking.

We are continuing to consider the financial impact of this modified approach, and are also considering other modifications to the design of the

Shared Savings Program that may be needed along with an administratively established benchmarking methodology, including potential changes to the program's participation options and financial models (level of risk and potential reward). We seek comment on any additional modifications to the design of the Shared Savings Program that should be considered in conjunction with administratively set benchmarks.

Lastly, we note that a number of the features of an administratively established benchmarking methodology diverge from the benchmarking requirements under section 1899(d)(1)(B)(ii) of the Act and would require the use of our authority under section 1899(i)(3) of the Act. Under section 1899(i)(3) of the Act, in order to use a payment model other than the payment model described in section 1899(d) of the Act, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. Accordingly, we also seek comment on the extent to which the use of administratively set benchmarks might have the potential to improve the quality and efficiency of care furnished to Medicare beneficiaries and any anticipated impact on Medicare expenditures. We will consider the information submitted as part of any determination of whether to propose in future rulemaking to implement aspects of an administratively-established benchmarking methodology in the Shared Savings Program.

c. Establishing an Administrative Benchmark Update Factor

(1) Overview

Under the administratively-established benchmarking concept, we would continue to utilize an ACO's historical FFS expenditures to establish the ACO's historical benchmark. However, we would modify the existing methodology to fully remove negative regional adjustments to the benchmark. We would otherwise retain much of the existing methodology for calculating the historical benchmark, including, if finalized, the proposed changes detailed in section III.G.5. of this proposed rule.

When setting the historical benchmark, we would continue to calculate the annualized and truncated per capita expenditures for beneficiaries who would have been assigned to the ACO using the 3 most recent years prior to the start of the agreement period for each of the four Medicare enrollment types. We would then trend the BY1 and BY2 expenditures forward to BY3, using the existing blend of national and regional FFS expenditure growth rates, adjust for health risk using the CMS–HCC model, and apply benchmark year weights to the trended, risk-adjusted expenditures for each Medicare enrollment type. The benchmark year weights would remain as follows: for new ACOs, BY1 (10 percent), BY2 (30 percent), BY3 (60 percent), and for ACOs in their second or subsequent agreement period, each benchmark year is weighted equally.

As described in the following sections, we would apply an alternative approach to annually updating the ACO's historical benchmark, using an OACT-projected ACPT factor, and applying a discount to the benchmark update to support savings to the Medicare program; the discount factor would vary based on the ACO's regional efficiency to converge benchmarks gradually between ACOs with higher and lower spending compared to their regions. We also further explain that with the use of a discount factor, we would no longer apply a negative regional adjustment. We conclude this section with an overview of the steps for the calculation for the administratively-established benchmark update factor.

(2) Use of Accountable Care Prospective Trend in the Benchmark Update

We are considering an approach that would transition the proposed three-way blend between the prospective ACPT and retrospectively determined regional and national growth rates (as described in section III.G.5.c. of this proposed rule) to an entirely prospectively set trend. This approach would further decouple benchmark updates from growth in realized FFS expenditures, thereby strengthening incentives for ACOs to participate in the Shared Savings Program and achieve savings.

OACT annually develops and publishes United States Per Capita Cost (USPCC) growth projections for Medicare spending. As described in section III.G.5.c. of this proposed rule, we are proposing that OACT would calculate an ACPT, based on a modification of the existing USPCC growth projections used annually for establishing Medicare Advantage rates. We envision that an ACPT, with some additional modifications as described below, would serve as the core component of the administratively set benchmark update under the longer-term approach.

We are considering how to calculate and apply the ACPT in a manner that maintains a consistent national benchmark update trend across ACOs for a given performance year, independent of when the ACO's agreement period began. We are considering an approach under which we would establish an ACPT every 5 years which would apply during that 5-year window. For example, if we were to establish an average annual trend for the years 2025 through 2029, we would then calculate a new average annual trend for the years 2030 through 2034, then for 2035 through 2039, and so on for each subsequent period.[286] An ACO's update factor for a given performance year would be derived from the average annual trend established for the 5-year window that includes the applicable performance year.

For example, an ACO beginning its 5-year agreement period in 2025 would have a single update factor trend for all performance years under the agreement period. For illustration, Table V.D1 from the 2021 Medicare Trustees Report[287] projects overall per capita spending growth for Medicare Parts A and B at an annualized rate of 5.1 percent from a 2024 base year to what would be a fifth performance year in 2029. Note that this projected spending growth serves as an illustrative proxy for what a corresponding ACPT might show, though it is based on a different methodology that is not customized to the mix of spending categories included in Shared Savings Program benchmark calculations. In contrast, an ACO beginning its 5-year agreement period in 2027 would have one trend rate for its first 3 performance years (2027, 2028, and 2029) and another for its last 2 performance years (2030 and 2031), as the update factor would be reset every 5 calendar years. This update factor would not change for the duration of the 5-year period in response to changes to the OACT projection, with the exception of an adjustment for changes to the price and demographic components of the ACPT trend as described below, or to account for extreme and uncontrollable circumstances. We would plan to continue to apply the update factor as a flat dollar, risk-adjusted amount, consistent with the methodology for the

[286] ACPT 5-year growth projection trends include different growth rates for each year within the 5-year projection. However, for the purposes of simplicity, the overall average annualized growth rate over the 5-year period would be utilized, such that the growth rate is constant over each of the 5 years. Price and demographic projections would be considered at an annual level for the purposes of the adjustment for forecasting error.

[287] *https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf.*

proposed use of ACPT in a three-way blend described in section III.G.5.c. of this proposed rule.

We are considering further refinements to calculating the ACPT as part of a longer-term approach for updating benchmarks using entirely administratively set update factors. For example, we are considering maintaining separate projections within the ACPT for price growth, volume/intensity growth, and demographic factors (with potential exceptions for certain service types such as Part B drugs, which are not currently projected using disaggregated growth assumptions). This disaggregation of these factors could be utilized in ACO benchmark updates (for service types where possible), as ACOs are anticipated to have impacts on volume/intensity growth but have minimal impact on price growth and demographic factors. Therefore, the ACPT volume-intensity trend would be held constant for the duration of the agreement period, but retrospective adjustments could be made annually to account for any differences between projected and actual price growth and demographic factors. This would mitigate the effects of unexpected changes in assignable beneficiary demographics, as well as of inflationary pressures or other price changes on ACOs benchmarks. We would also incorporate adjustments to the ACPT to account for changes in relative price levels across counties, as has been done in other ACO initiatives that use national trend projections, such as the Next Generation ACO Model.

By incorporating annual adjustments for changes in price and demographics, we expect that the administrative growth projection will exceed the observed volume/intensity growth, as ACOs generate savings relative to the growth projection. However, we are considering adding potential guardrails to the administrative growth projection in early years to ensure that forecasting error does not unfairly penalize ACOs or discourage participation. One option is to phase-in the administrative trend over the first 5 years, increasing the weighting of the administrative trend component of the update in the three-way blend calculation from 33 percent in PY1 to 50 percent in PY2, 75 percent in PY3, and 100 percent thereafter. Another option would be to limit the contribution of forecasting error to savings and loss calculations during the first 5 years of the new methodology. For example, a floor could be set such that the national mean benchmark could not fall more than 2 percent below national mean FFS spending. CMS may consider applying either or both of these guardrail options as part of a prospectively-set update factor.

As detailed in section III.G.5.c. of this proposed rule, we are proposing a prior savings adjustment with a 50 percent scaling factor for renewing and re-entering ACOs. Together, this proposed change and the changes to the benchmark update described in this RFI would act to limit the impact of an ACO's performance on its own benchmark. Increasing the 50 percent scaling factor for prior savings adjustments could be considered to further limit the impact of rebasing. The prospective update factor would remove this link within an agreement period and the prior savings adjustment would mitigate the impact of rebasing between agreement periods. After benchmarks converge to a regional baseline (as discussed in section III.G.7.d. of this proposed rule), the link between an ACO's savings and its subsequent benchmark would be severed completely. We anticipate that these changes would create and improve long-term incentives for ACOs to generate savings.

We would also need to establish a process for considering additional factors when recalculating the ACPT prospective update factor every 5 years. One factor may be the size of the accrued wedge between benchmarks and realized FFS spending. It is vital that ACOs are permitted to retain savings in subsequent agreement periods for there to be a strong incentive to generate savings. Allowing a permanent wedge between benchmarks and FFS spending is also vital to giving ACOs flexibility to meet patient needs by providing care that has been traditionally unreimbursed under FFS, such as care management programs or services addressing social needs. Should this wedge grow excessive, however, the update trend may need to be slowed to recover more savings for the Medicare program and its beneficiaries. Over time, updated OACT ACPT projections would also come to reflect the impact of ACOs on spending, and therefore we may need to use other external indices as factors in determining the preset benchmark update factor to ensure that ACOs continue to retain accrued savings.

We seek comment on these considerations for calculating an ACPT to be used as an administratively set benchmark update factor. We seek comment on the 5-year intervals for establishing an ACPT, and alternative approaches that would tie the ACPT to an ACO's agreement period. We also seek comment on approaches to accounting for price growth and demographic factors versus volume/intensity and considerations for guardrails to protect against projection error. Finally, we seek comment on approaches to updating the ACPT that would ensure it does not overly reflect ACOs' collective impact on spending.

(3) Discount Factor

Under the approach we are considering for implementing a common risk-adjusted regional benchmark (described in section III.G.7.d. of this proposed rule) that encourages participation by both historically efficient (spending below regional average) and inefficient (spending above regional average) ACOs, we believe there would need to be a period of gradual convergence in spending between efficient and inefficient ACOs, while allowing benchmarks for both to remain above realized FFS spending as ACOs generate savings. Therefore, we are seeking comment on the approach of subtracting a modest annual discount factor from the fixed 5-year ACPT growth trend based on the relative efficiency of the ACO. For example, if the projected ACPT trend was 5.1 percent annual growth, an ACO with a 0.2 percent discount factor would have a benchmark update factor based on a 4.9 percent annual growth rate (5.1 percent minus 0.2 percent). Overall, these discount factors would be intended to provide realistic targets that encourage participation by ACOs and providers and suppliers with spending above their regional average. Once in the program, these ACOs and providers and suppliers would have incentives to generate savings, and thus, gradually converge their spending more in line with historically lower spending ACOs.

To determine what discount would be applied to an ACO's update factor, we would calculate a measure of the ACO's regional efficiency. We would compare the ACO's historical spending (the weighted-average spending for the ACO in benchmark year 3 to a regional benchmark (the weighted-average regional FFS expenditures for benchmark year 3). This calculation would be similar to the approach used to determine the difference between the average per capita expenditures for the ACO's regional service area, and the average per capita amount of the ACO's historical benchmark under § 425.601(a)(8)(ii)(A). The discount would vary according to the regional efficiency of each participating ACO but, importantly, would not grow if an ACO successfully lowers spending (as it would under the current regional

adjustment methodology). Sample discount factors are shown in Table 70. If an ACO's historical spending was greater than its regional benchmark, we would apply a discount to the amount of the benchmark update, scaled such that a larger discount is applied for ACOs with increasingly higher spending (less efficient) compared to their regional benchmark. No discount would be applied to the update amount for ACOs with spending 2 percent or more below their regional benchmark. Applying larger discount factors to less efficient ACOs would converge benchmarks towards regionally consistent levels, allowing CMS to remove negative regional adjustments as further discussed in section III.G.7.c.(4) of this proposed rule while still driving convergence.

TABLE 70: Sample Discount Factors for ACOs with Varying Regional Efficiency

Regional Efficiency	Discount Factor
ACO historical spending > 1.05 * regional benchmark	0.333%
1.00 * regional benchmark < ACO historical spending <= 1.05 * regional benchmark	0.200%
0.98 * regional benchmark < ACO historical spending <= 1.00 * regional benchmark	0.100%
ACO historical spending <= 0.98 * regional benchmark	0.000%

We have observed that ACOs make significant changes in composition of ACO participant TINs during an agreement period, by adding and removing ACO participants. To account for ACO participant TIN changes, we would recalculate the ACO's discount factor for each performance year of the agreement period based on its regional efficiency using the composition of its ACO participant TINs for the applicable performance year. That is, we would use the ACO's certified ACO participant list for the performance year to determine the ACO's historical spending based on expenditures for the beneficiaries who would have been assigned to the ACO in benchmark year 3 and determine the ACO's regional service area for calculating the ACO's regional benchmark, and thus its regional efficiency.

We seek comment on this approach for calculating and applying a discount factor in determining the amount of an ACO's benchmark update. We seek comment on the intervals of the discount we described, and alternative approaches such as use of a sliding scale in determining the discount amount. We also seek comment on approaches to ensuring the discount is reflective of the ACO's regional efficiency, including the approach of recalculating the discount factor to reflect changes in an ACO's regional efficiency as a result of changes in the ACO's composition during its agreement period.

(4) Removal of Negative Regional Adjustments to the Benchmark

In accordance with § 425.601(a)(8), we apply a regional adjustment in establishing the ACO's historical benchmark, which is equal to a percentage of the difference between the average per capita amount of expenditures for the ACO's regional service area for BY3 and the ACO's historical benchmark.

In the administratively-established benchmarking concept, we would no longer apply negative regional adjustments to the benchmark, although positive regional adjustments would remain. Under this approach, ACOs with higher than average historical spending would begin with a benchmark calculated solely using their historical experience. This would encourage providers and suppliers with higher historical spending relative to their region to participate in the Shared Savings Program, while continuing to reward ACOs with lower-than-average historical spending for their efficiency relative to their region. This approach builds on the policies proposed in section III.G.5.c.(5) of this proposed rule to mitigate the impact of the negative regional adjustment on ACOs, particularly those caring for high-risk populations.

We are also considering approaches for addressing a potential concern that efficient ACOs would be disincentivized from adding less efficient providers and suppliers as ACO participants because it would reduce their regional adjustment. One approach would be to scale an ACO's initial, larger positive regional adjustment based on the overlap in beneficiaries that would have been aligned to the ACO using the ACO's initial ACO participant list and its updated ACO participant list. In this way, an ACO with spending below its regional average would retain its advantage conferred by the regional efficiency adjustment under its initial ACO participant list (to the extent it retains those ACO participants) while also being able to pursue the expanded savings opportunity afforded by the new benchmarking approach by adding less efficient providers and suppliers to its ACO participant list.

We seek comment on this approach, and considerations related to removing the negative regional adjustment in establishing the ACO's historical benchmark under an administratively-established benchmark approach. We also seek comment on considerations for limiting disincentives for efficient ACOs to add less efficient providers and suppliers.

(5) Detailed Administratively-Established Benchmark Update Calculation

The following is a step-by-step example of the administratively-established benchmark update calculation on which we are seeking comment:

- *Step 1:* Calculate the historical benchmark according to the existing Shared Savings Program benchmarking methodology (including, if finalized, the proposed changes detailed in section III.G.5. of this proposed rule), without applying negative regional adjustments.
- *Step 2:* Risk-adjust the historical benchmark to account for changes in severity and case mix between BY3 and the performance year for each enrollment type.
- *Step 3:* Apply the update factor to the risk-adjusted historical benchmark for each enrollment type, calculated as follows:

++ Start with the overall OACT-projected Shared Savings Program ACPT 5-year projected trend [288]

[288] As described in section III.G.5.c. of this proposed rule, we are proposing that OACT would develop a Shared Savings Program-specific ACPT to incorporate into the update factor calculation. This projected trend would vary from the USPCC projections designed for MA payment purposes in that adjustments would be made to make it applicable to ACO spending calculations, including

Continued

applicable for the ACO based on the start of its agreement period and the performance year for each enrollment type.[289] The update rate over an agreement period may include ACPT projected trends from more than one 5-year period if the ACO's agreement period does not align with the 5-year cycle for ACPT calculation.

++ Apply the average projected trend based on the number of years between BY3 and the performance year.

++ Apply any retrospective adjustments to the trend based on divergence between the price and demographic components of the ACPT projected trend and observed price trends and demographic changes. This retrospective adjustment would be calculated annually after the end of each performance year only for the price and demographic components (no such adjustment would be made for the volume-intensity component).

++ Subtract the relevant discount factor (as per the examples in Table 70, based on the regional efficiency of the ACO in BY3) from the adjusted trend for each year between BY3 and the performance year to determine the ACO's trend percentage.

++ Multiply the ACO's trend percentage by the average national ACPT value for assignment eligible beneficiaries (adjusted to reflect the ACO's relative risk in each eligibility category) to determine the flat dollar update amount.

++ Apply any guardrails as described in section III.G.7.c.(2) of this proposed rule.

++ Add the flat dollar update amount to the ACO's risk-adjusted historical benchmark for the applicable enrollment type.

• *Step 4:* Calculate a single per capita benchmark amount by taking a weighted average across each enrollment type.

d. Convergence to Regional Benchmarks; Post-Convergence Phase

Ultimately, this administratively-established benchmark approach would be partially intended to drive ACOs towards regional spending convergence, such that the Shared Savings Program could consider further benchmarking changes under which benchmarks would be established on a regionally consistent risk-adjusted basis across ACOs in the same area. This post-convergence phase would completely eliminate ratcheting effects by removing rebasing and would also decouple benchmarks from an ACO's historical spending, thereby creating a sustainable benchmarking approach that would support high ACO participation levels and reward ACOs for increased efficiency.

Regionally consistent benchmarking has precedent in other CMS models and programs. Medicare Advantage benchmarks are established using beneficiary risk scores and the Medicare Advantage Ratebook of county risk-standardized benchmarks, as described in §§ 422.258 and 422.306. In the ACO REACH Model,[290] the baseline component of the benchmark will be calculated either entirely or in part using a rate book with county benchmark expenditures and beneficiary risk scores. The Shared Savings Program calculates risk-adjusted county FFS expenditures for individual calendar years using a comparable approach, as discussed in section III.G.5.d. of this proposed rule.

ACO benchmarks in this post-convergence phase would be calculated based on a rate book of risk-standardized average per capita rates at the county level and beneficiary level risk scores. Crucially, the initial per capita county rates would reflect the average benchmark levels in the county, inclusive of the accrued wedge between benchmarks and realized spending, as opposed to reflecting average expenditures. An ACO's benchmark would be the product of its average beneficiary risk score, weighted by assigned beneficiary months, and its average regional benchmark rate, calculated as the weighted average of the county rates, weighted by the number of months of experience contributed by assigned beneficiaries residing in each county. The administratively set update factor described above would continue to be applied to ACO benchmarks in the post-convergence phase to determine average benchmark growth. As an example, say an ACO has assigned beneficiaries that reside entirely in two counties (County A and County B), with 50 percent of the assigned beneficiary population in each county. If the rate book rate for County A is $1,300 per beneficiary per month (PBPM) and the rate for County B is $1,100 PBPM, then the ACO's average regional benchmark rate would be $1,200 PBPM. If the ACO's assigned beneficiaries have an average risk score of 1.5, then the risk-adjusted benchmark would be $1,800 PBPM, pending application of the update factor. A regionally consistent benchmarking approach as described above would likely involve an annual determination of county rates tied to the publication of the rate book.

The convergence phase would be intended to converge benchmarks toward some level above realized spending, but below predicted spending absent ACOs, assuming ACOs generate savings. We are considering several approaches for developing county per capita rates. One method under consideration would be to calculate risk-standardized average per capita expenditures and apply a scalar adjustment that accounts for prior savings or the accrued wedge. Alternatively, another approach could involve developing county rates by calculating a weighted average benchmark across ACO-assigned and unassigned beneficiary populations in the county. In either case, we would continue to use an administratively-established factor to update county rates over time; however, we anticipate the need for a process to monitor the size of the wedge within a region (the risk-adjusted difference between the benchmark and FFS spending) and to establish bounds that restrict regional rates from exceeding a certain level above FFS spending.

We anticipate that the convergence phase will last between 5–10 years, depending on participation rates and the pace of spending convergence within regions. We expect ACO spending will converge within regions under the changes described in preceding sections of this RFI because the incentives for providers and suppliers with high spending for their region to participate in ACOs and lower spending would be much stronger, and the ACOs in which those providers and suppliers participate would have strong savings potential. Convergence in risk-adjusted spending may also be fostered by improvements to the risk adjustment methodology. Convergence in spending would not have to be complete, however, to transition to a post-convergence phase in which benchmarks are set based on a common regional rate that is risk-adjusted for an ACO's aligned population characteristics. We expect some continued variation in ACO spending, but the convergence to regional rates would still provide all ACOs an opportunity to lower spending below their benchmarks. Still, the timing for

adding back hospice and removing IME, DSH, and uncompensated care payments (as is already done for benchmarking under the Global and Professional Direct Contracting Model and will continue when the model transitions to the redesigned ACO REACH Model on January 1, 2023).

[289] The ACPT would include trends for Aged & Disabled (A&D) and End Stage Renal Disease (ESRD) beneficiaries. The Aged & Disabled trend would apply for the disabled, aged/dual eligible, aged/non-dual eligible enrollment types.

[290] See the ACO REACH Request for Applications at *https://innovation.cms.gov/media/document/aco-reach-rfa.*

transitioning to the post-convergence phase is important, as it may cause a significant shift in benchmarks for many ACOs as the baseline component shifts from population-specific to regionally consistent. In order to maintain participation, it would be essential that this phase does not occur until a sufficient portion of providers are below the administratively projected regional benchmark.

If the convergence phase takes longer than 5 years, we would need to address the potential rebasing effects for ACOs renewing for subsequent agreement periods under the new benchmarking approach. One approach would be to completely eliminate rebasing, and use the historical benchmark period from an ACO's first agreement period under the new benchmarking approach for subsequent agreement periods until the post-convergence phase. This approach would most directly eliminate rebasing effects, but would risk weakening the accuracy of the historical baseline expenditures as the number of years separating the baseline period and performance year increases. In prior rulemaking, we have acknowledged concerns about an approach that depends on older historical data in benchmark calculations (see, for example, February 2016 proposed rule, 81 FR 5832 through 5834, 5865 and 5866), including operational complications and potential biases that result from use of older historical data when the ACO's composition of providers and suppliers changes over time. These complicating circumstances may become more pronounced with a longer convergence period and a larger gap between the historical benchmark and performance period. An alternative approach would be to continue to use a baseline period of 3 years directly proceeding the start of the agreement period, but with ACO-specific adjustments to limit rebasing effects. For example, we are considering approaches that would build on the proposal, discussed in section III.G.5.c. of this proposed rule, to add prior ACO savings into subsequent benchmarks, with weighting to address changes in ACO composition.

We seek comment on—

- Considerations for the design of a regionally consistent benchmarking approach, including how to set fair and accurate risk-standardized benchmarks, the process for annual updates to regional rates, and how to distinguish between enrollment types.
- Considerations for the required conditions and timing for reaching this post-convergence phase with the use of regionally consistent benchmarks, as well as incentives to promote ACO spending convergence within a region.
- Approaches to addressing rebasing effects for renewing and re-entering ACOs in subsequent agreement periods during the convergence phase.
- Considerations for converging to nationally consistent spending versus regionally consistent spending.

e. Request for Comment on Addressing Health Equity Through Benchmarking

Consistent with the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985), we are committed to advancing equity in health and healthcare for all individuals and addressing inequities that exist in our policies and programs that serve as barriers to equal opportunity. The term ''equity'' is defined in E.O. 13985 as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment . . . .''

Benchmarks based on historically observed spending may be inequitable to the extent that historical patterns reflect existing inequities in both access to care and the provision of care. We are interested in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. Direct increases to benchmarks for historically underserved populations would grant additional financial resources to health care providers accountable for the care of these populations, and may work to offset historical patterns of underspending that influence benchmark calculation. Furthermore, setting payment in excess of current spending for groups experiencing disadvantage would incentivize ACOs to attract those groups with care and enhancements valued by these beneficiaries. Pairing such benchmark changes with monitoring of use of resources, quality, and outcomes can ensure that increased benchmarks are being used to address care inequities, rather than solely generating increased shared savings potential for ACOs benefitting from positive benchmark adjustments.

The redesigned ACO REACH Model [291] will be implementing a benchmark adjustment to address historical health inequities within CMS ACO initiatives, with the intent of incentivizing ACOs to seek out and form relationships with historically underserved beneficiaries. The ACO REACH benchmark adjustment is calculated at the beneficiary level, and provides for a $30 per beneficiary per month (PBPM) increase to an ACO's benchmark for each assigned beneficiary classified as being in the top decile of underserved beneficiaries across all beneficiaries in the ACO REACH Model. The adjustment is designed in a budget neutral manner, in which benchmarks will be reduced by a smaller $6 PBPM adjustment for each assigned beneficiary classified as being in the bottom five deciles. Beneficiaries will be stratified using a composite measure that incorporates a combination of ADI (percentile score from 1–100) and Dual Medicaid Status (Medicare only vs. Full or Partial Dual Eligibility). The area-level measure (Area Deprivation Index) [292] captures local socioeconomic factors correlated with medical disparities and underservice, while the beneficiary level measure (Dual Medicaid Status) captures economic challenges directly affecting individual beneficiaries' ability to access high-quality care. Because ADI is measured as a percentile (continuous variable), while Medicaid Status is a binary metric, a simple blending of the variables would underweight the ADI. Therefore, CMS will calculate the measure by starting with the ADI for a given beneficiary's census block group of residence (scored from 0–99 based on percentile relative to the nation), and applying a 25-point increase to the score for dually eligible beneficiaries. For example, a dually eligible beneficiary residing in a census block group with an ADI in the 75th percentile would receive a score of 75 + 25, for a total of 100.

Each ACO will then receive a net benchmark adjustment based on the number of its assigned beneficiaries in each category. For example, an ACO with 100 beneficiaries scoring in the top decile and 500 beneficiaries in the bottom five deciles in a given month would receive a net neutral benchmark impact for that month [($30 PBPM × 100)—($6 PBPM × 500) = 0].

The ACO REACH health equity benchmark adjustment addresses

[291] See the ACO REACH Request for Applications at *https://innovation.cms.gov/media/document/aco-reach-rfa.*

[292] The University of Wisconsin Neighborhood Atlas website (*https://www.neighborhoodatlas.medicine.wisc.edu/*) Area Deprivation Index was developed by researchers at the University of Wisconsin based on a measure developed by the Health Resources and Services Administration (HRSA) over 3 decades ago. It has been adapted to the Census Block Group level and includes factors measuring income, education, employment, and housing quality, which have been linked to a number of healthcare outcomes, to rank neighborhoods by socioeconomic disadvantage.

inequity in benchmarks calculated primarily using historical expenditures, where historical underspending for underserved beneficiaries informs benchmarks. In the context of the benchmarking approach outlined elsewhere in this section of this proposed rule, our intent would be to converge spending to the point where benchmarks can be calculated on a regionally consistent basis, which would address equity concerns associated with entrenched historical underspending. By utilizing risk-standardized regional rates to derive benchmarks, rather than blends of historical and regional spending that can entrench inappropriately low levels of spending for populations with unmet needs, the new benchmarking approach would facilitate setting benchmarks above current levels of spending for providers caring for underserved populations. Such adjustments could be implemented within the estimation of the predictive model of spending used for risk adjustment (the CMS–HCC model) or in a post-estimation benchmark adjustment as in ACO REACH so that benchmarks would support optimal rather than current spending for historically marginalized groups. These adjustments would not only act to correct resource disparities but also establish incentives for ACOs to attract underserved groups with enhanced care.

Likewise, these and other approaches could be employed to preserve (if not expand) existing payment differentials that set payment higher for certain providers. Equity-motivated benchmark adjustments could be implemented, for example, to support additional funding for safety net providers (for example, CAHs, RHCs, and FQHCs). In other cases, add-on payments, such as DSH and IME, might continue to be carved out of ACO benchmarks and performance year expenditures, as they are now. We seek comment on other policy adjustments that should be considered for benchmark setting in the post-convergence phase.

We seek comment on—

- Approaches, generally, to addressing health inequities via the benchmark methodology for the Shared Savings Program, and specifically to incentivize ACOs to serve historically underserved communities.
- Considerations for what data would need to be collected on Medicare beneficiaries and their communities (for example, need for and access to health care providers, transportation, and social services) and what factors should be considered to identify underserved communities and adjust ACO benchmarks.
- Considerations for including a health equity benchmark adjustment in the Shared Savings Program in the near term comparable to the equity adjustment being tested within the ACO REACH Model.
- Considerations for addressing health inequities in the context of the benchmarking concept outlined in this section of this proposed rule.
- Considerations for monitoring and program integrity tools that would track the use of any health equity benchmark adjustments for the intended purposes.
- Considerations for whether benchmark adjustments for ACOs that include CAHs, RHCs, FQHCs, and REHs as ACO participants would improve care for rural and underserved populations and increase participation by these providers and suppliers in the Medicare Shared Savings Program.

H. Medicare Part B Payment for Preventive Vaccine Administration Services

1. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and its administration for the specified preventive vaccines—the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. Under sections 1833(a)(1)(B) and 1833(b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. Payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC). We note that many other preventive vaccine products are not specified for Medicare Part B coverage under section 1861(s)(10) of the Act, such as the shingles vaccine, and instead are covered and paid for under Medicare Part D.

Section 1861(s)(10)(A) of the Act, as amended by section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) includes the COVID–19 vaccine and its administration in the same subparagraph as the influenza and pneumococcal vaccines and their administration. We implemented this change in the interim final rule with comment period titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' published in the November 6, 2020 **Federal Register** (85 FR 71145 through 71150). In that rule, we established that payments for COVID–19 vaccines and vaccine administration would be made in the same manner as payments for the influenza and pneumococcal vaccines. In section III.H.5. of this proposed rule, we propose to permanently codify regulatory changes published in the November 6, 2020 IFC.

2. Refinement to the Payment Amount for Preventive Vaccine Administration

a. Background for Medicare Part B Payment for Administration of Influenza, Pneumococcal, HBV Vaccines

Vaccine administration services described under section 1861(s)(10) of the Act are not technically valued or paid under the PFS, as they are not included within the statutory definition of physicians' services in section 1848(j)(3) of the Act. Prior to CY 2022, we had based payment rates for the administration of these preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that we use to establish payment rates for the PFS. Payments for the administration of the preventive vaccines by these suppliers are geographically adjusted based on the location of where the service was performed. Under the Outpatient Prospective Payment System (OPPS), we assign a payment rate for administering these preventive vaccines and the payment rates are applicable for preventive vaccine administration services by hospitals and home health agencies. Certain other types of providers and suppliers, such as RHCs, FQHCs and critical access hospitals (CAHs), are paid based on reasonable cost for vaccine administration.

We provided a discussion in the CY 2022 PFS final rule on the history of the valuation of the three HCPCS codes, G0008, G0009, and G0010, which describes the services to administer an influenza, pneumococcal, and HBV vaccine, respectively (86 FR 65180 through 65182). We explained that we generally had established payment rates for the three codes based on a direct crosswalk to the PFS payment rate for CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Additionally, we stated that using this methodology resulted in reductions in

the payment rates for the preventive vaccine administration services over several years and raised concerns from interested parties. Therefore, we attempted to address the reduction in payment rates for these vaccine administration HCPCS codes in the CY 2020 and CY 2021 PFS final rules (84 FR 62798 and 85 FR 84626 through 84628, respectively) by maintaining the CY 2019 payment rate for all three codes.

In rulemaking for the CY 2022 PFS, we continued efforts to establish payment for vaccine administration services on a long-term basis. In the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining the payment amount for vaccine administration services. In the CY 2022 PFS final rule (86 FR 65183 through 65187), we discussed the feedback received from a wide variety of interested parties in response to our comment solicitation. In that rule, we explained that we agreed with commenters on the need to establish stable payment rates that consider the costs associated with administering the preventive vaccines included in the Part B preventive vaccine benefit. In particular, we agreed that the payment rates for administration of the influenza, pneumococcal and hepatitis B vaccines are too low and need to be adjusted to reflect the costs incurred by healthcare providers. Furthermore, we agreed with commenters who stated that we should decouple payment for these vaccine administration services from the crosswalk to the PFS and treat them independently.

Additionally, in the CY 2022 PFS final rule (86 FR 65185), we explained that based on the history and status of payment for preventive vaccine administration and given the concerns gathered through the comment solicitation we believed that we needed to act expeditiously to update payment rates for the administration of preventive vaccines paid under Medicare Part B, effective January 1, 2022. In addition, we believed that the timing was appropriate for establishing a predictable payment rate for preventive vaccine administration since the PHE had ignited a hypervigilance for infectious diseases.

Therefore, for CY 2022, we finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine covered under the Medicare Part B preventive vaccine benefit at section 1861(s)(10) of the Act. We explained that since the administration of the preventive vaccines described under section 1861(s)(10) of the Act are finalized independent of the PFS, that these payment rates will be updated as necessary independently of the valuation of any specific codes under the PFS.

b. Background for Medicare Part B Payment for Administration of COVID–19 Vaccines

In the CY 2022 PFS final rule we stated that under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine and its administration through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website.[293] We also provided a detailed history on how the initial payment rates for the administration of the COVID–19 vaccines were determined and how the payment policy evolved to a rate of $40 per dose (86 FR 65181 and 65182).

As discussed above in this section, in the CY 2022 PFS proposed rule (86 FR 39220 through 39224) we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining a payment amount for preventive vaccine administration. As part of the comment solicitation, we requested feedback specifically related to the circumstances and costs associated with furnishing the COVID–19 vaccines to ensure we took these into consideration when determining our payment policy. In the CY 2022 PFS final rule (86 FR 65185), we discussed the feedback received in response to our comment solicitation with regard to the COVID–19 pandemic. In that rule, we recognized that the PHE has posed and continues to pose unique challenges for vaccination providers, particularly with respect to the administration of vaccines for COVID–19. For example, we anticipate that healthcare providers will continue to experience unusual costs associated with staffing, scheduling, and reporting requirements as increasing numbers of patients receive additional doses and boosters of the COVID–19 vaccines in the near future, and as health care providers adapt their vaccine delivery infrastructure accordingly. However, after the PHE, we anticipate that these costs will go down as patient volumes stabilize and as healthcare providers incorporate tasks such as scheduling and reporting into their routine clinical practice. For example, while we may see annual vaccination for COVID–19 similar to influenza, these vaccinations may happen in a more predictable manner, which would provide healthcare settings more time and ability to plan ahead for future vaccination needs. In addition, we noted that healthcare providers will have already made certain capital investments associated with the COVID–19 vaccines, such as ultra-cold storage freezers and software upgrades, during the course of the PHE, and thus, after the PHE such investments will no longer represent a significant additional cost over and above the costs of administering other preventive vaccines. For example, we believe recurrent staffing costs for COVID–19 vaccines may mirror the staffing needs for the administration of the yearly influenza vaccine. At the same time, we recognized that the formal termination of the PHE will not necessarily coincide with an immediate return to pre-pandemic circumstances, and that some of the additional costs mentioned above may persist while conditions normalize. For these reasons, we believed that it was appropriate to establish a single, consistent payment rate for the administration of all Part B preventive vaccines following the end of the calendar year in which the PHE expires. That is, effective January 1 of the year following the year in which the PHE ends, the $40 payment rate for administration of the COVID–19 vaccines will be adjusted to align with the payment rate for the administration of other Part B preventive vaccines (86 FR 65185).

c. Proposed Adjustment to the Payment Amount for Administration of Preventive Vaccines for Geographic Locality

Our method of paying for the administration of preventive vaccines has varied over time. Prior to March 1, 2003, we paid for the administration of an influenza, pneumococcal, or HBV vaccine, at the same rate as CPT code 90782 for the year corresponding to the date of service on the claim.[294] For dates of service on or after March 1, 2003 through December 31, 2021, the vaccine administration payment rates for an influenza, pneumococcal, or HBV vaccine were established through notice-and-comment rulemaking using a crosswalk to the payment rate for similar services paid under the PFS,

[293] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[294] Pub. 100–04, Chapter 18, Section 10.2.5.2. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c18pdf.pdf.*

such as, CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*) or CPT code 36000 (*Introduction of needle or intracatheter, vein*). Using the direct crosswalk to a similar service under the PFS requires applying the PFS payment calculation. This formula that uses a HCPCS code's relative value units (RVUs) for work, practice expense (PE), and malpractice (MP) adjusted by the location where the service is furnished (that is, geographic practice cost indices (GPCIs)). The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the average national costs for furnishing the service. Thus, in order to calculate the payment for the vaccine administration codes, the work, PE, and MP RVUs are adjusted by the GPCIs to reflect the variations in the costs of furnishing the services.

For CY 2022, we decoupled payment for these vaccine administration services from the PFS crosswalk and finalized a payment rate of $30 for the administration of an influenza, pneumococcal, or HBV vaccine and a payment rate of $40 for the administration of COVID–19 vaccines. However, in the CY 2022 PFS final rule, we inadvertently neglected to address a geographic adjustment policy for these payment rates and instead, noted only that payments would be geographically adjusted. When we posted the CY 2022 payment rates for preventive vaccine administration to the seasonal influenza web page, we posted locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rate.[295] Similarly, when we posted the CY 2022 payment rates for the COVID–19 vaccine administration to the COVID–19 vaccine web page, we posted locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rate.[296]

In this proposed rule, we are proposing a geographic adjustment policy that would apply to preventive vaccine administration services for CY 2023 and subsequent years. We continue to believe that it is appropriate to adjust the payment amount for the administration of preventive vaccines to reflect cost differences for each geographic locality. For example, suppliers' costs for rent or employee wages could vary significantly across different geographic areas. We also continue to believe that the geographic variation in costs of administering preventive vaccines provided by suppliers such as physicians, NPPs, and mass immunizers is similar to the geographic variation in the cost of physicians' services paid under the PFS.

Since we have decoupled payment for these vaccine administration services from the PFS crosswalk and finalized a payment rate for them, we believe the next step in establishing appropriate payment for preventive vaccine administration services independent of the PFS would be to consider a more independent approach to geographic payment adjustment. The PFS GPCIs reflect cost differences for each geographic locality for each of the three distinct components of PFS services (work, PE, and MP). In contrast, the payment rate we have established for administration of the flu, pneumococcal, and HBV preventive vaccines is a flat rate payment of $30, and for the administration of COVID–19 vaccines is a flat rate payment of $40. As such, a single adjustment factor could be used to apply the geographic locality adjustment for these services. In addition to calculating the three component GPCIs (work, PE and MP) to adjust payment under the PFS, under section 1848(e)(2) of the Act, we also calculate a Geographic Adjustment Factor (GAF) for each fee schedule area and, as we explain below, we are proposing to use this GAF described in § 414.26 to geographically adjust payment for preventive vaccine administration services beginning for CY 2023. Specifically, we are proposing to use the GAF to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas. The GAF is calculated using the three component GPCIs under the PFS (work, PE, and malpractice), and is calculated for each PFS fee schedule area as the weighted composite of all three GPCIs for each fee schedule area using the national GPCI cost share weights. The GAF, which is described under our regulation at § 414.26, is further discussed in section II.D. of this proposed rule, and the specific proposed GAF values for each fee schedule area are posted in Addendum D to this proposed rule.

We also considered continuing to adjust the payment amount for administration of preventive vaccines by applying the PFS GPCIs to reflect cost differences for each geographic area. However, to effectuate this adjustment, this method would require a crosswalk to the RVUs established under the PFS for a CPT code that describes a similar service and is reflective of the mix of work, PE and MP for preventive vaccine administration services. Having recently disconnected payment for preventive vaccine administration services from the PFS through rulemaking as explained above, we did not believe it would be appropriate to continue connecting these payments to the PFS in this way for purposes of geographic adjustment.

We have opted to propose use of the GAFs to adjust payment for the preventive vaccine administration services for geographic cost differences beginning for CY 2023. As we discuss above and in the CY 2022 PFS final rule (86 FR 65180–65194), we engaged the preventive vaccine community and established a stable payment amount for preventive vaccine administration that is based on resource costs. Since calculation of the GAFs incorporates the fundamental relative cost structure of the PFS GPCIs, but is a single factor that is weighted by the overall relative share of the three PFS component GPCIs, we believe application of the single GAF to geographically adjust the payment rate for preventive vaccine administration services based on costs in a given locality would be a more appropriate, streamlined approach to geographic adjustment that results in similar payment. Additionally, this method avoids the need to refer to the component RVUs for any particular reference service that is valued under the PFS, and thus gets us closer to updating the preventive vaccine administration rates independent of the PFS.

We propose to amend our regulation at § 410.152 to codify the use of the GAFs for each PFS fee schedule area to adjust payment amounts for the preventive vaccine administration services (influenza, pneumococcal, HBV, and COVID–19) to reflect the cost differences in furnishing these services in different fee schedule areas. We note that under this proposal, beginning January 1, 2023 we would apply the GAF to the $40 payment amount for COVID–19 vaccine administration service so long as the EUA declaration is still in place, as discussed in section III.H.4.d.i. of this proposed rule. We also note that we discuss payment for the administration of COVID–19 monoclonal antibody products in section III.H.4. of this proposed rule.

We invite public comment on our proposal to adjust the payment amount for the administration of preventive vaccines for geographic cost variations using the GAF. We also welcome comments on any other factors that could be used to make this payment adjustment to reflect geographic cost differences.

[295] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.*

[296] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

In this proposed rule, we are also proposing to amend our regulations to codify the payment amount established for administration of preventive vaccines in the CY 2022 PFS final rule and the proposed method for adjusting this rate for cost differences in each geographic locality. We note, as discussed in section III.H.2.d. of this proposed rule, we are proposing additional revisions to § 410.152 to reflect an annual adjustment to the payment amount for administration of preventive vaccines to reflect changes in cost using the Medicare Economic Index (MEI).

We also note that § 410.152(h) currently contains outdated payment policies for pneumococcal vaccine administration. Therefore, in this proposed rule we propose to revise § 410.152 by replacing the current paragraph (h) to reflect the following:

- Effective January 1, 2022, the established payment amount under Medicare Part B for administration of influenza, pneumococcal, and HBV vaccines is $30. For preventive vaccines administered January 1, 2022 through December 31, 2022, payments under Medicare Part B for administration of preventive vaccines are adjusted to reflect geographic cost variations using the GPCIs established under the PFS and the RVUs for a designated reference code under the PFS. Beginning January 1, 2023, we would adjust the payment amount for the administration of preventive vaccines for geographic cost variations using the GAF described in § 414.26.
- Effective January 1, 2022, the established payment amount under Medicare Part B for administration of COVID–19 vaccines is $40. For COVID–19 vaccines administered January 1, 2022 through December 31, 2022, payments under Medicare Part B for administration of COVID–19 vaccines are adjusted to reflect geographic cost variations using the GPCIs established under the PFS and the RVUs for a designated reference code under the PFS. Beginning January 1, 2023, we would adjust the payment amount for the administration of COVID–19 vaccines for geographic cost variations using the GAF described in § 414.26.
- Effective January 1 of the year following the year in which the PHE ends, the payment rate for administration of the COVID–19 vaccines will be adjusted to align with the payment amount for the administration of other Part B preventive vaccines. We note, as discussed in section III.H.4.d.i. of this proposed rule, we are proposing to clarify that this policy would be dependent on the declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), that is, EUA declaration for drugs and biological products.

We solicit comment on these proposals and the proposed amendments to the regulation text.

d. Proposed Annual Adjustment to the Payment Amount for Administration of Preventive Vaccines To Reflect Changes in Cost

As part of the comment solicitation in the CY 2022 PFS proposed rule, we requested feedback on whether CMS should use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis. Some commenters provided feedback in response to this specific inquiry. One commenter suggested that incremental updates should be made to the payment rate each year. Another commenter stated that annual updates to the vaccine administration payment rates based on OPPS claims data would be a reliable and data-based method for updating the payment rate and would prevent the issues that have occurred in the past with the crosswalk under the PFS to CPT code 96372. In response to those comments, we stated that we would continue to seek feedback on an appropriate mechanism for updating these payments on a yearly basis by, for example, applying an annual inflation factor, for example the increase in the MEI, to the payment rate in order to reflect increases in costs faced by providers and suppliers that furnish the service; and that we plan to address updating the payment rate for Part B preventive vaccine administration in future rulemaking.

We believe that finalizing a $30 payment amount that is adjusted for geographic locality for the service to administer preventive vaccines in CY 2022 was the first step in the development of a Part B payment methodology that provides predictable payment to the providers/suppliers furnishing these vaccines. For CY 2023, we discuss below how we propose to annually update the $30 payment amount to account for changes in costs associated with furnishing the service.

To account for the change in costs of administering preventive vaccines, we are proposing to update the payment amount (that is, $30) established in the CY 2022 PFS final rule for the administration of preventive vaccines based upon the annual increase to the MEI. The MEI is defined in section 1842(i)(3) of the Act and is used to update payment amounts in other healthcare settings. For example, the MEI is used to update the non-drug component of the OTP payment bundle and is also used to update the fixed-dollar payment amount for the originating site facility fee for Medicare telehealth services. The MEI is a fixed-weight input price index that reflects the physicians' own time and the physicians' practice expenses, with an adjustment for the change in economy-wide, private nonfarm business total factor productivity. The MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264) and the proposal to rebase and revise the MEI for CY 2023 can be found in section II.M. of this proposed rule. The current forecast of the increase in the MEI for CY 2023 is 3.8 percent based on the proposed 2017-based MEI. We note that the CY 2023 MEI increase factor for the final rule will be based on historical data through the 2nd quarter of 2022.

In developing the proposed method to update the payment amount for administering preventive vaccines, we considered other potential update factors, such as the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*). The Consumer Price Index for All Items (CPI–U) is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. However, we concluded that a healthcare-specific update factor, such as the MEI, would be more appropriate for suppliers that administer preventive vaccines than the CPI–U, which measures general inflation, as the MEI would more accurately reflect the change in the prices of goods and services included in the vaccine administration service. We also considered using a labor-specific series for the inflation factor since a main source of the expenses related to the administration of vaccines are related to the staff who administer them. For example, we considered the Employment Cost Index (ECI)—Wages and salaries for All Civilian workers in Hospitals (current forecast through CY 2023 is 4.2 percent) or the ECI—Wages and salaries for All Civilian workers in Health care and social assistance (current forecast through CY 2023 is 3.8 percent). However, we concluded that an update factor that takes into account other costs, such as the MEI, would be more appropriate for suppliers that administer preventive vaccines than the ECI.

We note that under this proposal, beginning January 1, 2023 we would

update the $40 payment amount for COVID–19 vaccine administration service based upon the proposed 2017-based MEI so long as the EUA declaration is still in place, as discussed in section III.H.4.d.i. of this proposed rule. We also note that we discuss payment for the administration of COVID–19 monoclonal antibody products in section III.H.4. of this proposed rule.

Accordingly, we propose to annually update the payment amount for administration of preventive vaccines based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We propose to codify this proposal in tandem with the revisions discussed above in section III.H.2.c. of this proposed rule under § 410.152. We invite public comment on this proposal. We also welcome comments on potential approaches to updating payment rates for administration of preventive vaccines other than the MEI that could be used as an annual adjustment to account for the change in costs associated with administering preventive vaccines.

e. Summary of Proposals and Implementation

In summary, for CY 2023 we propose to annually update the payment amount for the administration of Part B preventive vaccines based upon the increase in the MEI. Additionally, we propose to adjust this payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered using the GAF. These adjustments would apply to HCPCS codes G0008, G0009, and G0010 effective January 1, 2023.

With regard to COVID–19 vaccine administration, we stated in the CY 2022 PFS final rule that we will maintain the current payment rate of $40 per dose, which is geographically adjusted as described above, for the administration of the COVID–19 vaccines through the end of the calendar year in which the ongoing PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines. For example, if the COVID–19 PHE ends in CY 2022, the payment amount for COVID–19 vaccine administration would change from $40 to $30 effective January 1, 2023, and we would apply the proposed geographic adjustments and the proposed annual update as proposed for the other preventive vaccine administration services as discussed above. We note, as discussed in section III.H.4.d.i. of this proposed rule, we are proposing to clarify that this policy would be dependent on the declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products. Several CPT codes used for billing COVID–19 vaccine administration and a list of effective COVID–19 vaccine administration codes is available on the CMS web page.[297]

3. In-Home Additional Payment for Administration of COVID–19 Vaccines

a. Background

On June 9, 2021, we announced a new add-on payment with a national rate of approximately $35.00 when a COVID–19 vaccine is administered in the home, and on August 24, 2021, we expanded the circumstances under which the in-home add-on payment is available.[298] [299] Under this policy, providers and suppliers that administer a COVID–19 vaccine in the home under certain circumstances can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes [300] along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). The total national average payment to providers and suppliers administering a COVID–19 vaccine in the home is $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home), and both payments are geographically adjusted using PFS GPCIs as discussed in section III.H.2.c. of this proposed rule. In the CY 2022 PFS final rule (86 FR 65187 and 65188), we provide a detailed explanation on how the payment amount was established. In announcing the add-on payment for in-home COVID–19 vaccine administration, we noted that we established these policies on a preliminary basis to ensure access to COVID–19 vaccines during the public health emergency and that we will continue to evaluate the needs of Medicare patients and these policies, and address them in the future, as needed.

In the CY 2022 PFS proposed rule (86 FR 39224 through 39226), we included a comment solicitation to collect feedback on these policies and potential future changes. As part of the comment solicitation, we requested feedback related to our definition of ''home'', program integrity concerns, changes that we should consider, costs associated with administering COVID–19 vaccines in the home, and whether outside of a PHE there is a need to vaccinate people in the home rather than going to a health care provider or supplier. In the CY 2022 PFS final rule (86 FR 65188 through 65190), we discussed the feedback received and that commenters overwhelmingly recommended that we continue making the additional payment beyond the end of the PHE, with many also supporting extending the payment to other preventive vaccines, either permanently or until the end of the PHE. Commenters emphasized the importance of increasing vaccination rates and making vaccines available to vulnerable homebound beneficiaries who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources.

In that rule, we agreed with commenters that the added costs and compelling needs required CMS to adopt the in-home add-on payment rate for COVID–19 vaccine administration. In addition, we stated that since we did not expect those needs or costs to diminish immediately with the end of the PHE, we believed it would be appropriate to leave the in-home add-on payment rate in place through the end of the CY in which the PHE ends. For example, we anticipated that additional COVID–19 vaccine booster doses will be needed. In addition, we believed that that this policy would set clear expectations for vaccine providers and suppliers and allow for a more gradual transition to a permanent payment policy.

Therefore, we finalized continuation of the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances until end of the calendar year in which the PHE ends. As we discussed in the CY 2022 PFS final rule, extending the availability of the in-home add-on payment past the end of the PHE maximizes access to COVID–19 vaccines for vulnerable homebound beneficiaries during the gradual return to normal conditions following the formal termination of the PHE. We also explained that this

[297] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[298] *https://www.cms.gov/newsroom/press-releases/biden-administration-continues-efforts-increase-vaccinations-bolstering-payments-home-covid-19.*

[299] *https://www.cms.gov/newsroom/press-releases/cms-expands-medicare-payments-home-covid-19-vaccinations.*

[300] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

extension of payment past the end of the PHE affords CMS the opportunity to monitor vaccine uptake data (86 FR 65189).

b. Conditions for Billing HCPCS Code M0201

In establishing the additional payment for COVID–19 vaccine administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. In the CY 2022 PFS final rule, we provide a detailed discussion on how we established the certain conditions under which the code can be used, and the situations we contemplated to arrive at our final payment policy (86 FR 65187 and 65188).

For purposes of this add-on payment for in-home COVID–19 vaccine administration, the following requirements apply when billing for HCPCS code M0201: [301] [302]

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

++ They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

++ They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

++ They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID–19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be:

++ A private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter);

++ An apartment in an apartment complex or a unit in an assisted living facility or group home (including assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program);

++ A patient's home that is made provider-based to a hospital during the PHE for COVID–19; or

++ Communal spaces of a multi-unit or communal living arrangement.

- A home cannot be:

++ An institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[303]

The COVID–19 vaccine must be administered inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. HCPCS code M0201, as noted in the code descriptor, can be billed only once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.

c. Proposal for CY 2023

Subsequent to the CY 2022 PFS final rule, we have received suggestions from interested parties that this in-home add-on payment should be applied more broadly to all preventive vaccines, and concerns that discontinuation of the payment would negatively impact access to preventive vaccines for vulnerable homebound beneficiaries. While we agree with these concerns, we also believe that we need to learn more about the populations served through the current in-home add-on payment, and other potential populations that may not have been able to access a COVID–19 vaccine despite the availability of the in-home add-on payment, to understand the barriers they face in receiving vaccinations in their home versus in the community. We also need to consider potential program integrity concerns.

We believe continuing the additional payment for at-home COVID–19 vaccinations for another year would provide us time to track utilization and trends associated with its use to inform the policy for CY 2024. At this time, we are not extending the policy to include the other preventive vaccines. One of the reasons we established this rate is to account for the post-administration time that the health care professional must spend in the home to monitor the patient after administration of the COVID–19 vaccine. Administration of the COVID–19 vaccine typically involves monitoring the patient for at least 15–30 minutes post-injection which is not the general administration protocol for other vaccines. The in-home add-on payment helps to account for the costs associated with special handling of the vaccine and the extra time spent with the patient when a vaccine is administered in the home.

Therefore, for CY 2023 we propose to continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under the certain circumstances described above in section III.H.3.b of this proposed rule. We are also proposing to adjust this payment amount for geographic cost differences as we do the payment for the preventive vaccine administration service. That is, for CY 2023, we would adjust this payment amount to reflect cost differences for the geographic area based upon the fee schedule area where the COVID–19 vaccine is administered using the GAF. In addition, for CY 2023, we would update the $35.50 by the CY 2023 MEI as we proposed to do for the other preventive vaccine administration services. Both proposals are discussed above in section III.H.2.c. and III.H.2.d. of this proposed rule, respectively. We believe that this policy will continue to provide access to beneficiaries who would otherwise have difficulty getting vaccinated, while we continue to monitor utilization and receive information to be considered in developing our policy for the future. We welcome comments and suggestions on steps we could take related to program integrity and beneficiary protections associated with payments for administering preventive vaccines in the home, including the COVID–19 vaccine and other preventive vaccines under Medicare Part B.

4. Clarification on Policies for COVID–19 Vaccine and Monoclonal Antibody Products

a. Background

Under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), the Secretary can declare a public health emergency (PHE) if he determines that: (1) a disease or disorder

[301] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[302] *https://www.cms.gov/files/document/vaccine-home.pdf.*

[303] 42 CFR 409.42(a).

presents a PHE; or (2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. A PHE declaration allows the Secretary to take certain actions in response to the PHE. In addition, a PHE declaration under section 319 of the PHS Act can be a necessary step in authorizing the Secretary to take a variety of discretionary actions to respond to the PHE under the statutes HHS administers.[304] If the criteria under section 564 of the FD&C Act are met, the Secretary may make a declaration that the circumstances exist justifying an emergency use authorization (EUA) of unapproved drugs, devices, or biological products, or of approved drugs, devices, or biological products for an unapproved use.[305]

On January 31, 2020, under section 319 of the PHS Act, the Secretary determined that a PHE as a result of confirmed cases of 2019 Novel Coronavirus existed nationwide and had existed since January 27, 2020 (hereafter referred to as the PHE for COVID–19). The Secretary has since renewed this declaration for successive 90-day periods, most recently on April 12, 2022.[306] On March 27, 2020, the Secretary declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section (85 FR 18250 through 18251). This latter declaration enabled the Commissioner of Food and Drugs to issue an EUA for a drug or biological product if the Commissioner reasonably concludes that, among other criteria, based on the totality of available scientific evidence, the product may be effective in diagnosing, treating or preventing such disease or condition, and the product's known and potential benefits when used to diagnose, prevent, or treat such disease or condition, outweigh its known and potential risks.

b. Timing Distinction Between Section 319 of the PHS Act and Section 564 of the FD&C Act Declarations

Declarations under section 319 of the PHS Act generally last for 90 days, but may be extended [307] by the Secretary. After each extension, the declaration lasts for 90 days or until the Secretary declares the emergency no longer exists, whichever occurs first. In contrast, an emergency declaration pursuant to section 564 of the FD&C Act (an ''EUA declaration'') continues until specifically terminated.[308] An EUA declaration may remain in effect beyond the duration of the section 319 PHE declaration. When an EUA declaration is to be terminated, notice of termination will be published in the **Federal Register** that provides a reasonable period of advance notice to the public that the EUA declaration is being terminated, to permit manufacturers, health care facilities, providers, patients, and other interested parties to transition away from EUA products and the policies that support them.

c. Medicare Part B Coverage and Payment of COVID–19 Vaccine and Therapeutic Monoclonal Antibody Products

At the time of drafting this proposed rule, three COVID–19 vaccines are authorized or approved for use in the US to prevent COVID–19.[309] FDA has approved licensure of Pfizer-BioNTech and Moderna COVID–19 mRNA vaccines for use in certain individuals, but there are also individuals for whom these vaccines continue to be available under an EUA. FDA has limited the authorized use of the Janssen-manufactured COVID–19 viral vector vaccine to individuals 18 years of age and older for whom other FDA-authorized or licensed COVID–19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID–19 vaccine because they would otherwise not receive a COVID–19 vaccine. In addition, there are other COVID–19 vaccines that are not licensed or authorized under an EUA, but are in Phase 3 clinical trial.[310]

Regarding availability of COVID–19 monoclonal antibody products, there are no monoclonal antibody products approved for the treatment or prevention of COVID–19. There are five authorized monoclonal antibody COVID–19 products; four are authorized for the treatment of COVID–19 and one is authorized as pre-exposure prophylaxis for prevention of COVID–19.[311] We note that each of the four monoclonal antibody products for treatment or post-exposure prevention of COVID–19 that have been granted an EUA is not authorized for use in geographic regions where infection was likely caused by a non-susceptible variant. Due to data indicating decreased activity for three of these treatments against Omicron variants currently in wide circulation, only one of these treatments is currently authorized in any U.S. region until further notice by FDA.

In the interim final rule with comment (IFC) period titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the November 6, 2020 **Federal Register**, we discussed how we believed it is appropriate for Medicare to consider any EUA under section 564 of the FD&C Act issued for a COVID–19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a vaccine to be described in section 1861(s)(10)(A) of the Act (85 FR 71145 through 71148). That is, even though section 3713 of the CARES Act refers to a COVID–19 vaccine ''licensed under section 351 of the PHS Act,'' CMS could consider any vaccine for which FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, to be eligible for Medicare coverage and payment.

Subsequent to the November 6, 2020 IFC and discussed in the CY 2022 PFS final rule (86 FR 65190 through 65194), when COVID–19 monoclonal antibody products were granted EUAs during the PHE for COVID–19, we made the determination to cover and pay for them under the Part B vaccine benefit in section 1861(s)(10) of the Act. This determination effectively extended the policy decision for COVID–19 vaccines to COVID–19 monoclonal antibody products, that is, that an EUA under section 564 of the FD&C Act issued for a COVID–19 monoclonal antibody

[304] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/PHE-Questions-and-Answers.pdf.*

[305] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.*

[306] *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx.*

[307] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[308] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.*

[309] Viewed 5/6/2022. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#about-vaccines.*

[310] Viewed 5/6/2022. *https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine.*

[311] Viewed 5/6/2022. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

product during the PHE is tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a COVID–19 monoclonal antibody product to be described in section 1861(s)(10)(A) of the Act.

The decision to cover and pay for monoclonal antibody products used to treat COVID–19 under the Part B vaccine benefit prioritized access to these products during the COVID–19 pandemic by allowing almost all Medicare enrolled providers and suppliers, as permitted by State law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care. Covering and paying for these services under the Part B vaccine benefit also means that beneficiaries are not responsible for any cost sharing for the product or the service to administer it.

We note that under the Part B preventive vaccine benefit, Medicare pays for the vaccine product (when such product is not free to the provider/supplier, as is the case for COVID–19 vaccines as of the publication of this rule) and its administration. Typically, payment for the vaccine product is made at 95 percent of the AWP, but some healthcare settings, such as RHCs, are paid at 100 percent of their reasonable cost. Typically, payment for the administration of the preventive vaccine shots is approximately $30 per dose, but again, some healthcare settings are paid at 100 percent of their reasonable cost. In contrast, payment for administration of COVID–19 monoclonal antibody products under the Part B preventive vaccine benefit depends on the route of administration, and whether the product is furnished in a healthcare setting or in the beneficiary's home. As discussed in more detail in the CMS COVID–19 Monoclonal Toolkit, payment for administration of monoclonal antibodies can range from $150.50 to $750.00.[312]

In the CY 2022 PFS final rule (86 FR 65179 through 65193) we discussed several steps CMS has taken to promote broad and timely access to COVID–19 vaccines and monoclonal antibody products used to treat COVID–19 paid for under the Part B preventive vaccine benefit, during the PHE for COVID–19. We specifically discussed the unique circumstances providers and suppliers face when administering COVID–19 vaccines and recognized the difficulty to predict when resource costs relating to COVID–19 vaccination will align with those for other vaccinations after the PHE ends, as we believe the scale of this PHE is unique in Medicare payment history. We finalized the policy to maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the PHE ends; effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate that aligns with the per dose payment rate for administration of other Part B preventive vaccines (86 FR 65186).

In the CY 2022 PFS final rule, we contemplated how to cover and pay for COVID–19 monoclonal antibody products following the end of the PHE for COVID–19, including whether we should align their payment and coverage with other biologicals (86 FR 65190 through 65194). After review of the comments received, we agreed with commenters who recommended CMS transition to treating monoclonal antibody therapies used to treat COVID–19 as biologicals that are paid using methodologies under section 1847A of the Act following the end of the calendar year in which the PHE expires. We noted that Medicare considers other monoclonal antibody products—that is, monoclonal antibody products used in the treatment of other health conditions—to be ''biologicals,'' and Medicare pays for them based on the methodology in section 1847A of the Act when they are furnished in physician offices or ambulatory infusion clinics, and under a similar methodology under the hospital OPPS. For these care settings, we typically rely on the applicable AMA CPT codes to describe and pay for drug administration services performed by providers and suppliers.

In the CY 2022 PFS final rule, we also explained that the public health needs that prompted coverage of monoclonal antibody products used to treat COVID–19 paid for under the Medicare Part B vaccine benefit will gradually stabilize following the end of the PHE, and that extending the current payment approach to the end of the year will give healthcare providers adequate time to prepare for the change in payment methodology while continuing to maximize access to beneficiaries, including those who receive these treatments in the home. In addition, we stated that since we do not expect those needs or costs to diminish immediately with the end of the PHE, we believe it would be appropriate to continue to provide payment and coverage for COVID–19 monoclonal antibody therapies under the Medicare Part B vaccine benefit in place through the end of the CY in which the PHE ends, when such treatments are used consistent with the scope and conditions of authorization in the relevant EUA (while in effect). In the CY 2022 PFS final rule, we recognized that once an EUA declaration is terminated,[313] EUAs issued under that declaration will no longer remain in effect,[314] which may affect the availability of some products either for the diagnosis, treatment, or prevention of COVID–19, because they will need to have the requisite marketing authorization to remain on the market. To the extent there are products that would no longer have the requisite marketing authorization to remain on the market after a revocation of an EUA, we believe a transition period would be appropriate to allow for adjustments, as needed, to care plans that included such products (86 FR 65192).

d. Clarification of Medicare Part B Policies

In light of the timing distinctions between a PHE declared under section 319 of the PHS Act and an EUA declaration under section 564 of the FD&C Act, we have reconsidered the policies finalized in the CY 2022 PFS final rule and believe a clarification is necessary. Throughout our discussions and specifically in policy statements related to payment and coverage for COVID–19 vaccines and monoclonal antibody products, we have used phrases such as, ''through the end of the calendar year in which the PHE ends'' and ''effective January 1 of the year following the year in which the PHE ends.'' While we acknowledge that the intent at the time was to refer to the declaration under section 319 of the PHS Act, we have reconsidered this position in light of the fact that the March 27, 2020 EUA declaration under section 564 of the FD&C Act is distinct from, and not dependent on, the PHE declaration under section 319 of the PHS Act. Therefore, an EUA for a drug or biological product issued pursuant to the March 27, 2020 EUA declaration may remain in effect beyond the duration of the section 319 declaration if all statutory conditions are met.[315] On further consideration, we believe that

[312] *https://www.cms.gov/monoclonal.*

[313] Subsequent to the issuance of the final rule, we found that we incorrectly stated 'once the COVID–19 PHE declaration is terminated.' The correct statement is 'once the EUA declaration is terminated.'

[314] *https://www.fda.gov/media/97321/download.*

[315] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.*

our goal to promote broad and timely access to COVID–19 vaccines and COVID–19 monoclonal antibody products, will be better served if our policies with respect to payment for these products, as addressed in the November 2020 IFC and CY 2022 PFS final rule, continue until the EUA declaration for drugs and biological products (see 85 FR 18250) is terminated. Therefore, we propose to clarify our policies as stated below. In section III.H.4.f of this proposed rule, Table 71 displays the CY 2023 Part B payment for preventive vaccine administration if the EUA declaration persists into CY 2023 and Table 72 displays the Part B payment for preventive vaccine administration beginning January 1, 2023, if the EUA declaration ends on or before December 31, 2022.

i. COVID–19 Vaccines and Their Administration

CMS will maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the payment rate for COVID–19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines. We note a summary of proposals for Part B preventive vaccine administration for CY 2023 is discussed in section III.H.2.e. of this proposed rule.

ii. In-Home Administration of COVID–19 Vaccines

We note that the policy for in-home administration of COVID–19 vaccines was also discussed in the CY 2022 PFS final rule and we finalized that CMS will continue the additional payment of $35.50 for COVID–19 vaccine administration in the home under certain circumstances through the end of the calendar year in which the PHE ends. However, in section III.H.3 of this proposed rule, we discuss proposals for this policy for CY 2023. We are proposing to continue the in-home additional payment of $35.50 for administering COVID–19 vaccines for CY 2023, which is no longer tied to the end of the declaration under section 319 of the PHS Act.

iii. Monoclonal Antibody Products Used for Treatment or for Post-Exposure Prophylaxis of COVID–19

We propose to continue to pay for COVID–19 monoclonal antibody products under the Medicare Part B vaccine benefit through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated. Until the end of the calendar year in which the EUA declaration for drugs and biological products is terminated, we will maintain the payment rate for administering a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19 in a healthcare setting, as well as the payment rates for administering a COVID–19 monoclonal antibody product in the home as described on the CMS COVID–19 Monoclonal Toolkit.[316] Effective January 1 of the year following the year in which the EUA declaration for drugs and biological products ends, CMS would pay physicians and other suppliers for covered COVID–19 monoclonal antibody products used for the treatment or for post-exposure prophylaxis of COVID–19 as biological products paid under section 1847A of the Act; healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID–19 monoclonal antibody therapies similar to the way they are paid for administering other complex biological products (86 FR 65192).

As we explain above, since an EUA for a drug or biological product issued pursuant to the March 27, 2020 EUA declaration may remain in effect beyond the duration of the section 319 declaration, we contemplated our proposed policies summarized in section III.H.2.e of this proposed rule. Since we do not know when FDA would terminate the March 27, 2020 EUA declaration, we believe that we need to give notice on how these proposals would impact payments for administering COVID–19 monoclonal antibody products in the event the EUA declaration persists in CY 2023. Therefore, beginning January 1, 2023, we propose to apply the GAF to the payment amount for the administration of monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID–19 so long as the EUA declaration is still in place. We believe that it is appropriate to continue to adjust this payment amount to reflect cost differences for each geographic area.

Regarding an update based upon the MEI beginning January 1, 2023, we would not extend the proposal to update the payment amount for the administration of these products. We believe that the payment amounts established for the administration of monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID–19 were approximations intended to reflect resource costs associated with furnishing these particular services during the pandemic response and generally corresponding to the time frame the EUA declaration is effective. We also note that some of the resource costs reflected in those rates, such as costs to establish the necessary operational infrastructure, may dissipate over time, even as the pandemic persists. Consequently, we do not believe it would be appropriate to establish annual updates to reflect increased costs that would likely be offset to some extent by reduced costs given the more established infrastructure and delivery approaches. We point out, too, that the current payment rates effective during the years in which the PHE continues correspond with OPPS New Tech payment amounts that are intended to serve as estimates of overall costs, in contrast to more finely tuned amounts that are typically subject to annual updates (increases or reductions) to reflect greater efficiency. Therefore, we are proposing to maintain the current rates for CY 2023 for administration of a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19, and to not update these rates based on the increase in the MEI.

e. Monoclonal Antibody Products Used as Pre-Exposure Prophylaxis for Prevention of COVID–19

As we mention in section III.H.4.c of this proposed rule, there are no monoclonal antibody products approved by the FDA for the treatment or prevention of COVID–19 as of the publication of this proposed rule. However, there are currently three COVID–19 products authorized under an EUA; two are authorized for the treatment of COVID–19, and one is authorized as pre-exposure prophylaxis for prevention of COVID–19.[317] The

[316] *https://www.cms.gov/monoclonal.*

[317] Viewed 5/6/2022. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

monoclonal antibody product for use as pre-exposure prophylaxis prevention of COVID–19 was granted an EUA subsequent to the CY 2022 PFS final rule. Therefore, our policies regarding coverage of COVID–19 monoclonal antibody products as finalized in the CY 2022 PFS final rule, and clarified in section III.H.4. of this proposed rule, do not address monoclonal antibody products used as pre-exposure prophylaxis for prevention of COVID–19. Nevertheless, we note that when this COVID–19 monoclonal antibody pre-exposure prophylactic product was granted an EUA, we promptly provided payment and coverage for it under the Part B vaccine benefit in section 1861(s)(10) of the Act as we discuss in section III.H.4.c and as we have done for the other COVID–19 monoclonal antibody products.[318]

We recognize that there are certain individuals for whom these pre-exposure prophylactic products may be their only preventive option against COVID–19. These individuals would include, for example, those who are not currently infected with COVID–19, who have not had a known recent exposure to an individual infected with COVID–19, and for whom vaccination with any available COVID–19 vaccine is not recommended due to a history of severe adverse reaction (for example, severe allergic reaction) to a COVID–19 vaccine(s) and/or COVID19 vaccine component(s). Therefore, we are proposing to clarify that our policy of coverage and payment under the Part B vaccine benefit for monoclonal antibody products includes those used as pre-exposure prophylaxis for prevention of COVID–19. In addition, to ensure the aforementioned beneficiaries have access to COVID–19 pre-exposure prophylactic products, we propose to continue the existing policy to pay for these products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

Since we propose to pay for pre-exposure prophylaxis monoclonal antibody products for COVID–19 under the Part B vaccine benefit, we also propose to apply the GAF to the payment amount for the administration of those monoclonal antibody products, effective January 1, 2023. However, at this time we are not proposing to update the payment amount with the MEI beginning January 1, 2023. The payment amounts established for the administration of monoclonal antibody products used as pre-exposure prophylaxis for COVID–19 were intended to account for resource costs associated with pandemic response, and like the payment amounts for administration of other COVID–19 mAbs, reflects an approximation. Therefore, we are proposing to maintain the current amount without a specified update mechanism, but also seek comment on how best to consider refining rates for administration of this specific kind of product in the future. We solicit comment on these proposals.

f. Summary of Payment Amounts for CY 2023 With or Without an EUA Declaration for Drugs and Biologicals

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products, and our proposed policies that plan for both a continuation or termination of that EUA, we are including Tables 71 and 72 that summarize our proposals in both scenarios.

TABLE 71: CY 2023 Part B Payment for Preventive Vaccine Administration if EUA Declaration Persists into CY 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Adjustment?	Geographic Adjustment?
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$30	MEI	GAF
COVID-19 Vaccine[2,4]	$40	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]			
Infusion: Health Care Setting	$450.00	N/A	GAF
Infusion: Home	$750.00	N/A	GAF
Intravenous Injection: Health Care Setting	$350.50	N/A	GAF
Intravenous Injection: Home	$550.50	N/A	GAF
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.

[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

[3] https://www.cms.gov/monoclonal.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] As of the issuance of the CY2023 PFS NPRM, this product is only available under EUA as injection.

[318] *https://www.cms.gov/monoclonal.*

TABLE 72: Part B Payment for Preventive Vaccine Administration Beginning January 1, 2023, if EUA Declaration Ends on or Before December 31, 2022

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Adjustment?	Geographic Adjustment?
Influenza, Pneumococcal, Hepatitis B[1,4]	$30	MEI	GAF
COVID-19[2,4]	$30	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	$150.50/$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered and beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] There are no monoclonal antibody products for pre-exposure prophylaxis of COVID-19 that have marketing authorization at this time.

5. Regulatory Updates and Conforming Changes

In the interim final rule with comment (IFC) period titled, ''Additional Policy and Regulatory Revisions in Response to the COVID– 19 Public Health Emergency,'' which appeared in the November 6, 2020 **Federal Register**, we published several changes to the regulations governing Part B preventive vaccines and their administration, in order to include the COVID–19 vaccine and its administration (85 FR 71147). Since Section 3713 of the CARES Act added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration, the COVID–19 vaccine was similarly added in several regulations regarding the influenza, pneumococcal, and hepatitis B virus (HBV) vaccinations. We intend to finalize the following regulatory changes, which were adopted in the November 6, 2020 IFC:

- § 410.152 (l)(1), which includes the COVID–19 vaccine to the list of vaccines for which Medicare Part B pays 100 percent of the Medicare payment amount.
- § 410.160 (b)(2), which includes the COVID–19 vaccine in the list of vaccines that are not subject to the Part B annual deductible and do not count toward meeting that deductible.
- § 411.15 (e)(5), which adds an exception for COVID–19 vaccinations to the general exclusion of coverage for immunizations.
- § 414.701, which includes the COVID–19 vaccine in the list of statutorily covered drugs.
- § 414.707 (a)(2)(iii), which includes the COVID–19 vaccine in the list of vaccines with a payment limit calculated using 95 percent of the AWP.
- § 414.900(b)(3), which includes the COVID–19 vaccine in the list of statutorily covered drugs.
- § 414.904(e)(1), which includes the COVID–19 vaccine in the list of vaccines with payment limits calculated using 95 percent of the AWP.

In the course of developing the proposed changes to § 410.152 described above at III.H.2.c., we came across several outdated and incomplete regulations regarding Part B preventive vaccines and vaccine administration. We propose updates and corrections to the following regulations:

- At § 410.10, Medical and other health services: Included services, we are proposing to amend paragraph (l) to list pneumococcal, influenza, and COVID–19 vaccines and their administration.
- At § 410.10, Medical and other health services: Included services, we are proposing to amend paragraph (p) to list both Hepatitis B vaccine and its administration, as defined in § 410.63(a).
- At § 410.57, we are proposing to amend the section title to read ''Preventive Vaccinations,'' to amend paragraph (a) to state only that Medicare Part B pays for pneumococcal vaccine and its administration, to remove the remainder of the outdated language, and to add paragraph (d) to state that Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).
- At § 410.63, Hepatitis B vaccine and blood clotting factors: Conditions, we are proposing to amend the introductory paragraph to replace the outdated reference to § 405.310 with an updated reference to § 411.15.
- At § 414.707, Basis of Payment, we are proposing to amend paragraph (a)(2)(iii) to replace the phrase in parentheses with ''as defined in § 410.63(a) of this subchapter.''
- At § 414.904, Average sales price as the basis for payment, we are amending paragraph (e)(1) to replace the parentheses with ''as defined in § 410.63(a) of this subchapter.''

I. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

1. Background-Nonemergency, Scheduled, Repetitive Ambulance Service

a. General Discussion

Section 1861(s)(7) of the Act states that, for the purposes of Medicare, the term ''medical and other health services'' includes ambulance services, but only ''where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations.'' Regulations at § 410.40 govern Medicare coverage of ambulance services. Under § 410.40(e), Medicare Part B covers ground (land and water) and air (fixed-wing and rotary-wing) ambulance transport services only if they are furnished to a

Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.

Section 410.40(e) provides that nonemergency transportation by ambulance is appropriate if either the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. For a beneficiary to be considered bed-confined, § 410.40(e) states that *all* of the following criteria must be met: (1) the beneficiary is unable to get up from bed without assistance; (2) the beneficiary is unable to ambulate; and (3) the beneficiary is unable to sit in a chair or wheelchair. Section 410.40(e) further provides that bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation, but is one factor that is considered in medical necessity determinations. In all cases, a beneficiary's condition must be documented appropriately for coverage of services.

In the ''Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements'' final rule with comment period [319] (64 FR 3637, January 25, 1999) (hereinafter referred to as the ''January 25, 1999 final rule''), we finalized language at § 410.40(d)(3) to require ambulance providers or suppliers, in the case of nonemergency, unscheduled, ambulance services to obtain a physician certification statement (PCS). There, we explained that: (1) nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible, and, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS would help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3648).

We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries. However, in the January 25, 1999 final rule we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician and agreed with interested parties that while it is reasonable to expect that an ambulance provider or supplier could obtain a pre-transport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance providers and suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we finalized a requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the ''Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services'' final rule with comment period [320] (67 FR 9100) (hereinafter referred to as the ''February 27, 2002 final rule''), in response to interested parties response, we modified our documentation regulations, noting that we had been made aware of instances in which ambulance providers and suppliers, despite having provided ambulance transports, were experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe through no fault of their own. We stated that the 48-hour period remained the appropriate period of time, but, with respect to unscheduled, or scheduled but non-repetitive nonemergency ambulance transports, created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(e)(3)(iii) where ambulance providers and suppliers unable to obtain a PCS from the attending physician could obtain a signed certification (*not* a physician certification statement) from certain other staff. At that time, we identified, at § 410.40 (a)(iii), several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints were: (1) that the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

Since being finalized in the February 27, 2002 final rule, § 410.40(e)(2) has stated that Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (e)(1) of this section are met (67 FR 9132).

In the November 16, 2012 final rule with comment period [321] (77 FR 68892), we finalized provisions currently at § 410.40(e)(2), incorporating nearly the same provision found at § 410.40(e)(3)(v) to clarify that a PCS does not, in and of itself, demonstrate that a nonemergency, scheduled, repetitive ambulance service is medically necessary for Medicare coverage. As we note above, the 1861(s)(7) definition of ''ambulance service'' in the context of Medicare expresses the clinical medical necessity requirement that the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations.

In the November 15, 2019 final rule [322] (84 FR 62568), in response to interested parties' requests, we clarified the requirements for certification statements based on potential confusion surrounding the format, content, and use of both PCS and non-physician certification statements. Further, we added licensed practical nurses (LPNs), social workers and case managers as individuals listed at § 410.40 (a)(iii) who may sign the non-physician certification

[319] *https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1547.pdf.*

[320] *https://www.govinfo.gov/content/pkg/FR-2002-02-27/pdf/02-4548.pdf.*

[321] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of NonRandom Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; *https://www.govinfo.gov/content/pkg/FR-2012-11-16/pdf/2012-26900.pdf.*

[322] Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule; *https://www.govinfo.gov/content/pkg/FR-2019-11-15/pdf/2019-24086.pdf.*

statement if the ambulance provider or supplier is unable to obtain the attending physician's signature within 48 hours of the transport.

Other factors have significantly altered the Medicare ambulance benefit, notably section 637 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted January 2, 2013) (ATRA), which required a 10-percent reduction in fee schedule payments for nonemergency (BLS transports of beneficiaries with ESRD) to and from both hospital-based and freestanding renal dialysis treatment facilities, for non-emergent dialysis services. Section 53108 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) increased the payment reduction of fee schedule payments for BLS transports to and from renal dialysis treatments, from ATRA's 10 percent to 23 percent.

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) has published numerous reports about Medicare's ambulance benefit and has concluded that this benefit is highly vulnerable to abuse. In September 2015, in a report titled, ''Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports,'' [323] the OIG reported that approximately one in five ambulance suppliers had questionable billing, and that suppliers that had questionable billing provided nonemergency basic life support transports more often than other suppliers.

In addition, in June 2013, MedPAC published a report that included an analysis of nonemergent ambulance transports to dialysis facilities. The report showed that transports to and from dialysis facilities continue to grow and represent a large share of non-emergent ambulance claims. In the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined. In 2011, ambulance transports to and from dialysis facilities accounted for nearly $700 million in Medicare spending or approximately 13 percent of Medicare expenditures on ambulance services. The report further found that certain States had dramatically higher spending on ambulance transportation for dialysis treatment than other States. We believe that the provisions that we propose here are consistent with MedPAC's recommendations that the agency promulgate national guidelines to more precisely define medical necessity requirements. This will ensure consistent application of the benefit across beneficiary populations, regardless of geographic location.

Under section 1115A of the Act, CMS initiated the testing of the Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Model, which tested whether prior authorization helped to reduce expenditures while maintaining or improving quality of care. Beneficiaries who qualify for these services are typically transported to receive either cancer treatment or dialysis, although there are other services for which this type of transportation is needed. Section 515 of the Medicare Access and CHIP Reauthorization Act (Pub. L. 114–10, enacted April 16, 2015) (MACRA), required this model to be expanded to include eight States and the District of Columbia, not later than January 1, 2016. Also in section 515 of MACRA, Congress amended section 1834(l) of the Act to require the model be expanded to all States, beginning January 1, 2017, to the extent that the expansion that Congress required above satisfied certain criteria specified at 1115A(c) of the Act.

We released two Interim Evaluation Reports [324] and a Final Evaluation Report [325] on the model. The Final Evaluation Report, similar to the two Interim Evaluation Reports, found that the model was successful in reducing nonemergency, scheduled, repetitive ambulance transport spending and total Medicare spending while maintaining the overall quality of and access to care. In comparison to groups of similar States, the model reduced nonemergency, scheduled, repetitive ambulance transport use by 72 percent and expenditures by 76 percent, for Medicare beneficiaries with end-stage renal disease (ESRD) and/or severe pressure ulcers in the model States, resulting in a reduction of approximately $750 million in expenditures. This decrease in nonemergency, scheduled, repetitive ambulance transport expenditures contributed to a 2.4 percent ($1 billion over the first 5 years of the model) decrease in total Medicare fee-for-service (FFS) expenditures among beneficiaries with ESRD and/or pressure ulcers relative to the comparison groups. Overall, the findings suggested that the model had few to no adverse effects on quality of care or access to care.

On March 28, 2018, CMS' Chief Actuary certified that expansion of the model would reduce program spending under the Medicare program, thereby satisfying the requirements of section 1115A(c)(2) of the Act for expansion of the model. Based on the CMS Chief Actuary certification and the first Interim Evaluation Report, the HHS Secretary determined that the model met the statutory criteria for expansion under sections 1115A(c)(1) and (c)(3) of the Act. Therefore, on September 22, 2020, CMS announced that it would expand the model nationwide under section 1834(l)(16) of the Act.[326] The 8 participating States and the District of Columbia were transitioned to the national model on December 2, 2020. After a delay due to the COVID–19 public health emergency, HHS began expanding the model nationwide through multiple phases starting on December 1, 2021. HHS continues the expansion throughout fiscal year 2022.

Inconsistent application of payments for medically necessary, nonemergent, repetitive, scheduled ambulance services has the potential to disproportionately and substantially impact communities of color, underserved communities (including rural communities), and modest-income beneficiaries. Further, these communities may disproportionately suffer from conditions for which nonemergent, repetitive, scheduled ambulance services are necessary, creating access to care issues with corresponding clinical complications. We believe that improving clarity in our regulatory provisions will have positive impacts on the health and well-being of beneficiaries. Therefore, we are proposing and requesting public comment on policy clarifications to ensure beneficiaries receive the care they need.

b. Legal Authorities

The legal authority for our proposed provision is section 1861(s)(7) of the Act that provides general authority for the ambulance benefit and grants the Secretary authority to prescribe regulations for the administration of the benefit.

2. Proposed Revision to § 410.40

We seek public comment on proposed language that clarifies documentation and medical necessity requirements for

[323] Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports (OEI–09–12–00351; 09/15) (*hhs.gov*).

[324] *https://innovation.cms.gov/files/reports/rsnat-firstintevalrpt.pdf* and *https://innovation.cms.gov/data-andreports/2020/rsnat-secondintevalrpt.*

[325] *https://innovation.cms.gov/data-and-reports/2021/rsnat-finalevalrpt.*

[326] *https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide.*

nonemergency, scheduled, repetitive ambulance services, by modifying § 410.40(e)(2)(ii).

Section 410.40 describes the Medicare Part B ambulance benefit, generally. Because medical necessity is a requirement of the statutory requirement at section 1861(s)(7) of the Act, the requirements for coverage are more fully explained in paragraph (e) of § 410.40, starting with general rules covering all Part B ambulance services, and the special rules that only apply to nonemergency, scheduled, repetitive ambulance services are situated in paragraph (e)(2). For the reasons discussed above, we propose to modify existing language in § 410.40(e)(2)(ii) and add additional language to provide needed clarity and ensure consistent application of the nonemergency, scheduled, repetitive ambulance service benefit. We solicit comments on our proposal.

We propose at § 410.40(e)(2)(ii) to retain the existing language stating that in all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS (OMB control number 0938–0969). We are maintaining the language that states that the ambulance service must meet all program coverage criteria including vehicle and staffing requirements. We are also maintaining the language that states that a signed PCS does not alone demonstrate that transportation by ground ambulance was medically necessary. We are clarifying that the PCS, and additional documentation from the beneficiary's medical record, may be used to support a claim that transportation by ground ambulance is medically necessary. Further, we are clarifying that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at 410.41(a). Finally, we are clarifying that coverage includes observation or other services rendered by qualified ambulance personnel, as described in 410.41(b).

J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment

1. Enrollment Process

a. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as discussed further in section III.J. of this proposed rule, we propose several changes to our existing Medicare provider enrollment regulations. (We note that section III.K of this proposed rule addresses a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

With respect to our Medicaid proposal in section III.K. of this proposed rule:

- Section 1902(kk)(3) of the Act,[327] as amended by section 6401(b) of the Affordable Care Act, which mandates that States require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.[328]
- Section 2107(e)(1) of the Act, as amended by section 6401(c) of the Affordable Care Act, which makes the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

2. Proposed Medicare Enrollment Provisions

a. Expansion of Authority To Deny or Revoke Based on OIG Exclusion and Associated Definitions

i. OIG Exclusions

Under §§ 424.530(a)(2) and 424.535(a)(2), respectively, CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or

[327] Because section 6401(b) of the Affordable Care Act erroneously added a duplicate section 1902(ii) of the Act, the Congress enacted a technical correction in the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) to redesignate section 1902(ii) of the Act as section 1902(kk) of the Act, a designation we will use in this final rule with comment period.

[328] Section 1304 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) added a new paragraph (j)(4) to section 1866 of the Act, thus re-designating the subsequent paragraphs. Accordingly, we are interpreting the reference in section 1902(kk)(3) of the Act to ''disclosure requirements established by the Secretary under section 1866(j)(4)'' of the Act to mean the disclosure requirements described in section 1866(j)(5) of the Act.

supplier is excluded by the OIG. We propose several changes related to these authorities.

First, we would expand the categories of parties listed within these denial and revocation provisions to include: (1) managing organizations; and (2) officers and directors of the provider or supplier if the provider or supplier is a corporation. Consistent with sections 1124 and 1124A of the Act (and depending upon the specific enrollment transaction and provider type involved), these parties must be reported on the provider's or supplier's Form CMS–855 or, for Medicare diabetes prevention program (MDPP) suppliers, the Form CMS–20134. Although they are not explicitly listed in §§ 424.530(a)(2) and 424.535(a)(2), we have generally considered these individuals and entities to be parties that exercise managing control over the provider or supplier in a vein similar to managing employees. Section 1124(a)(3) of the Act specifically includes officers and directors within its definition of persons with an ownership or *control* interest. (Emphasis added.). To clarify our longstanding position via rulemaking and to help prevent excluded managing organizations, officers, and directors from posing a program integrity threat to Medicare, we propose to incorporate these persons and organizations within the two aforementioned regulatory paragraphs.

ii. Definitions

In light of our addition of ''managing organization,'' ''officer'', and ''director'' to §§ 424.530(a)(2) and 424.535(a)(2), as well as some uncertainty in the provider community regarding the scope of these terms, we propose to define them in § 424.502.

''Managing organization'' would mean an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement. This definition mirrors the definition of ''managing employees'' in § 424.502, with the exception of the latter's references to individuals. To maintain consistency with the ''managing employee'' definition and to ensure that all parties exercising any degree of operational control over the provider or supplier are reported on the Form CMS–855 and Form CMS–20134 applications, we believe our proposed definition is appropriate.

We would define ''officer'' as an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity. Section 1124(a) of the Act requires the disclosure of officers if the entity is a corporation; we propose to include the same reference to corporations to align with this statutory provision. In addition, providers have sometimes inquired as to whether officers of a non-profit corporation must be reported. While section 1124(a) of the Act does not mention the for-profit or non-profit status of the corporation, we have always required non-profit corporation officers to be disclosed. In our view, the particular proprietary status of the corporation is less important from a program integrity standpoint than ensuring that persons who exercise control over the provider or supplier do not present payment safeguard risks. We believe this warrants the inclusion of non-profit corporations within our proposed definition.

In a similar context, we propose to define ''director'' as a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. To further clarify the definition, however, we propose that ''director'' includes any member of the corporation's governing body irrespective of the precise title of either the board or the member; said body could be a board of directors, board of trustees, or similar body. We have received questions over the years from non-profit corporations regarding the need to disclose information on the application about volunteer or ceremonial board members. We have long required such persons to be reported for two reasons. First, we believe section 1124(a) of the Act is clear that all directors must be listed. Again, it does not distinguish between for-profit and non-profit entities, nor, for that matter, between paid and voluntary board members. Therefore, we have concluded that our interpretation of section 1124(a) of the Act is fully consistent with the language therein. Second, the corporate governing body of a provider or supplier usually exercises clear control over the latter. Even if certain members, such as volunteers, have less day-to-day control of the provider or supplier than other members, they can still (depending on the board's specific powers) influence the entity's operations and oversight, perhaps more so than certain individuals currently included within §§ 424.530(a)(2) and 424.535(a)(2), such as administrative personnel. Consequently, we believe that our proposed definition of ''director'' aligns with both the Act and our existing policy.

iii. Contracted Personnel

We also propose to add a new paragraph to §§ 424.530(a)(2) and 424.535(a)(2) to clarify that the persons and entities listed in those two regulatory provisions include, but are not limited to, W–2 employees and contracted parties of the provider or supplier. We have traditionally applied §§ 424.530(a)(2) and 424.535(a)(2) to affected parties (such as supervising physicians) regardless of their W–2 status; this is consistent with the definition of ''managing employee'' in § 424.502, which does not exclude contracted personnel from its purview. We believe, and it has been our experience, that parties with whom the provider or supplier contracts are often as involved with the provider's or supplier's operations as W–2 employees; for instance, a provider may contract with medical personnel to furnish the majority of the health care services it furnishes. Given our stance that the specific employment status of the party is less crucial from a payment safeguard perspective than the fact that the person or entity is acting on the provider's or supplier's behalf, we believe that this regulatory clarification is needed.

Under this change, we would redesignate the introductory paragraph of existing § 424.530(a)(2) as § 424.530(a)(2)(i). Current §§ 424.530(a)(2)(i) and (ii) would be redesignated as § 424.530(a)(2)(i)(A) and (B), respectively. Our new paragraph concerning contracted personnel would be new § 424.530(a)(2)(ii). Similar structural revisions would be made to § 424.535(a)(2).

b. Expansion of Authority To Deny or Revoke Based on a Felony Conviction

Under §§ 424.530(a)(3) and 424.535(a)(3), respectively, CMS may deny or revoke enrollment if the provider or supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. We propose to expand these two regulatory provisions to include therein managing organizations, officers, and directors (as we proposed to define those terms in § 424.502.) As previously explained, we are obligated to protect the Medicare program, the Trust Funds, and beneficiaries. Similar to exclusions, we are concerned that persons and entities that have engaged in felonious behavior could, through their association with the provider or

supplier, present program integrity risks. We again acknowledge that, for instance, certain directors (in their individual capacity) might not have as much daily oversight of the provider's or supplier's operations as other persons within the organization. Yet we maintain that membership on a governing body involves the exercise of at least a minimum degree of control. Accordingly, we believe that our proposed expansion of §§ 424.530(a)(3) and 424.535(a)(3) is warranted.

For reasons similar to those behind proposed §§ 424.530(a)(2)(ii) and 424.535(a)(2)(ii), we would add new paragraphs at §§ 424.530(a)(3)(iii) and 424.535(a)(3)(iv) clarifying that these two provisions also apply to contracted parties.

c. Reversal of Revocation or Denial

Sections 424.535(e) and 424.530(c) state that if a revocation or denial, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification. To maintain consistency with our aforementioned changes to §§ 424.530(a) and 424.535(a), we propose to add managing organizations, officers, and directors to §§ 424.535(e) and 424.530(c).

d. Medicare Revocation Based on Other Program Termination

Sections 424.535(a)(12)(i) states, in part, that CMS can revoke enrollment if the provider or supplier is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any Federal health care program. However, under § 424.535(a)(12)(ii) revocation cannot occur unless and until the provider or supplier has exhausted all applicable appeal rights. The meaning of the latter language has caused uncertainty regarding situations where the provider or supplier does not appeal the program termination at all. Our position has always been that, in such cases, revocation under § 424.535(a)(12)(i) can ensue once the initial period to file an appeal has ended; that is, CMS need not wait until the expiration of every subsequent appellate period that would have applied had the provider or supplier appealed. To clarify this via rulemaking, we propose to add the language ''or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal'' to the end of § 424.535(a)(12)(ii).

e. Categorical Risk Designation—Ownership Changes and Adverse Actions

i. Background

Under the authority granted to us by section 6401(a) of the Affordable Care Act (which amended section 1866(j) to the Act), § 424.518 outlines levels of screening by which CMS and its MACs review initial applications, revalidation applications, and applications to add a practice location. These screening categories and requirements are based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three levels of screening in § 424.518: high, moderate, and limited. Irrespective of which level a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new location:

- Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
- Conducts State license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Furthermore, for those at the high screening level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are meant to correspond to the heightened risk involved.

There currently are only four provider or supplier types that fall within the high categorical risk level under § 424.518(c)(1): newly/initially enrolling home health agencies (HHAs); newly/initially enrolling DMEPOS suppliers; newly/initially enrolling Medicare Diabetes Prevention Program (MDPP) suppliers; and newly/initially enrolling opioid treatment programs (OTPs).

ii. Current Grounds for Risk Level Increase (or ''Bump Up'')

Under § 424.518(c)(3)(i) and (ii), CMS adjusts a particular provider's or supplier's screening level from ''limited'' or ''moderate'' to ''high'' if the provider or supplier:

- Has had a payment suspension within the previous 10 years;
- Has been excluded by the OIG;
- Has had its Medicare billing privileges revoked within the previous 10 years and is attempting to establish additional Medicare billing privileges by (i) enrolling as a new provider or supplier or (ii) adding a new practice location;
- Has been terminated or is otherwise precluded from billing Medicaid;
- Has been excluded from any Federal health care program; or
- Has been subject to any final adverse action (as defined at § 424.502) within the previous 10 years.

The screening level will also be raised to ''high'' under § 424.518(c)(3)(iii) if: (1) CMS lifts a temporary moratorium (per § 424.570) for a particular provider or supplier type; and (2) a provider or supplier that was prevented from enrolling (based on the moratorium) applies for Medicare enrollment within 6 months after the moratorium was lifted.

The general purpose of § 424.518(c)(3) is to ensure that providers and suppliers that have certain adverse actions imposed against them are reviewed with a concomitant level of scrutiny.

iii. Analysis

Section 424.518 was implemented in 2011, and we have been screening providers and suppliers in accordance therewith since then. However, we have been concerned that § 424.518 lacks clarity on two critical matters.

First, and as alluded to previously, § 424.518 outlines screening requirements for initial enrollment applications, revalidation applications, and practice location additions. Yet it does not specifically address:

- Change of ownership (CHOW) applications under § 489.18; or

• The reporting of a new owner when a formal § 489.18 CHOW is not involved (such as disclosing a new 10 percent owner per § 424.516(e)(1)).

Section 424.518's current dearth of clear applicability to these two situations effectively means that a high-risk level provider or supplier can have a new owner without the latter having to undergo the important scrutiny that fingerprint-based criminal background checks furnish. That is, in promulgating § 424.518 in 2011, we recognized the uniquely critical role that owners often play in the provider's or supplier's operations by restricting our fingerprinting requirement to such persons. To mandate the fingerprinting of owners with initial applications, revalidations, and new practice locations but not with the aforementioned two transactions that specifically focus on the disclosure of new owners would be both an inconsistency and a program integrity risk.

The second issue involves the risk-level elevation criteria in § 424.518(c)(3). There are numerous health care entities that have multiple enrollments under their organizational umbrella. (To illustrate, Health Care System X, Inc. may have within its corporate structure a small hospital, four physician groups, two skilled nursing facilities, a DMEPOS supplier, and an OTP provider, all of which are separately enrolled in Medicare but with Health Care System X, Inc. identified as their legal business name.) Situations can arise where an organization with multiple enrollments has had an action described in § 424.518(c)(3) imposed against it or against one of its enrollments. Consider the following examples:

• Example 1—Entity Y has three separately enrolled physician groups (A, B, and C), each at the limited-risk level of categorical screening. Group C has just been revoked under § 424.535(a)(1) for non-compliance with enrollment requirements.

• Example 2—Organization Z has within its structure an enrolled HHA, an enrolled nurse practitioner group, and an enrolled independent diagnostic testing facility (IDTF). The organization itself has recently been convicted of a felony (which is identified as a final adverse action under § 424.502). All three of its enrollments are accordingly revoked.

The adverse actions described in these two examples fall within the scope of events that would trigger an increase in risk level under § 424.518 to ''high.'' There has been uncertainty among interested parties, particularly provider organizations with multiple enrollments, as to the extent of the risk-level elevation in these cases. That is, the issue is whether an adverse action imposed with respect to a particular enrollment applies strictly to said enrollment or also applies to all of the provider's or supplier's other enrollments, meaning that the screening level for these additional enrollments would, too, be raised to ''high.'' Under this latter approach, which has generally been our policy, the following would occur under aforementioned Examples 1 and 2:

• Example 1—All initial enrollment applications, revalidations, and additions of practice locations involving Group Practice A, B, or C (for instance, Group C sought to re-enroll in Medicare after the expiration of its reenrollment bar under § 424.535(c)) would be processed at the ''high'' level of categorical screening. In addition, if Entity Y sought to enroll new Group Practice D, the latter's initial application would be subject to the ''high'' screening category.

• Example 2—As with Example 1, all of Organization Z's enrollments would be elevated to ''high'' under § 424.518(c)(3). If any of the revoked providers and suppliers sought to reenroll in Medicare after their reenrollment bars expire, their enrollments would be processed at the high-risk level.

We believe the foregoing approach is warranted because we have historically viewed § 424.518(c)(3) in the broad context of applying to the controlling provider or supplier at large and not necessarily being confined to one of its enrollments. The central consideration, in our view, is the risk that the behavior at issue poses to the Trust Funds and to the safety of our beneficiaries. Even if, for instance, a Medicaid termination occurred with only one of the entity's enrollments, this raises serious questions about the organization's oversight of the enrolled providers and suppliers under its control. We believe that the overriding need to protect the Medicare program justifies heightened examination of the other enrollments within the organization's domain.

iv. Specific Regulatory Revisions

Given the prior discussion and for reasons already outlined, we propose the following changes to § 424.518.

First, the opening paragraph of § 424.518 references initial applications, revalidation applications, and practice location additions as falling within § 424.518's purview. We propose to add to this paragraph the following transactions:

• Change of ownership applications under § 489.18.

The reporting of any new owner (regardless of ownership percentage) via a change of information or other enrollment transaction (such as a full or partial certified supplier ownership change) under Title 42.

Second, we propose to clarify in § 424.518(c)(1) that the provider and supplier types included therein—once enrolled—are subject to high-risk screening if they are submitting a § 489.18 change of ownership application or an application to report a new owner (as described in the previous paragraph). As a technical elucidation, we would also change the language in paragraph (c)(1) that reads, CMS has designated the following home health agencies and suppliers of DMEPOS as ''high'' categorical risk to CMS has designated the following provider and supplier types as ''high'' categorical risk. This would merely clarify that certain providers and suppliers other than HHAs and DMEPOS suppliers (such as OTPs) fall within the purview of paragraph (c)(1).

Third, the introductory language in § 424.518(c)(3) states that CMS adjusts the screening level from limited or moderate to high if any of the previously cited adverse actions against the provider or supplier occur. To clarify the extent of such adjustments, we propose to add a new paragraph (c)(4). We would state therein that any adjustment under paragraph (c)(3) would also apply to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification (TIN) number as the provider or supplier for which the risk level under (c)(3) was originally raised. We believe using an LBN–TIN combination as the barometer for application of (c)(3) to other providers and suppliers is proper for two reasons. First, providers and suppliers with the same LBN and TIN are generally closely related in certain legal and operational aspects (for instance, similar ownership or management). Such alignment between these parties, in our view, warrants a concomitant level of review in the event paragraph (c)(3) is invoked. Second, utilizing an LBN–TIN standard in paragraph (c)(4) would likely offer more clarity and definiteness for interested parties regarding paragraph (c)(3)'s applicability than a potentially more nebulous standard, such as ''within a common business structure.''

f. Categorical Risk Designation—Skilled Nursing Facilities (SNFs)

SNFs are currently in the limited-risk screening category under § 424.518. However, CMS in recent years has become increasingly concerned about certain problems within the SNF community, particularly potential and actual criminal behavior. Indeed, a specific concern raised in several government reports involves patient abuse. For instance, the United States Government Accountability Office (GAO) published an analysis on January 14, 2022 titled ''Health Care Capsule: Improving Nursing Home Quality and Information'' (GAO–22–105422). In this report, the GAO identified gaps in CMS' prior oversight of nursing homes that make it more difficult to prevent patient abuse. Another GAO report, titled ''Nursing Homes: Better Oversight Needed to Protect Residents from Abuse'' (GAO–19–433), was published in June 2019.[329] The study aimed to: (1) determine the trends and types of nursing home patient abuse in recent years; and (2) evaluate CMS' oversight that is intended to ensure residents are free from abuse. The report concluded, among other things, that patient abuse deficiencies found on State surveys more than doubled between 2013 and 2017.[330] It also noted inconsistencies as to when State survey abuse findings or allegations of abuse are referred to law enforcement.[331] The subject of background checks was also addressed. The GAO interviewed various interested parties and determined that nursing homes without adequate staff screening mechanisms (such as background checks) could result in hiring staff with histories of abuse.[332] It added that because ''staff screening through background checks and the nurse aide registry is not coordinated across the country, there are gaps that could enable individuals who committed crimes in one state to obtain employment at a nursing home in another state. . .Staff from a nursing home we visited said the prevention of abuse 'starts with hiring the right staff' and noted the importance of conducting background checks and checking references for prospective employees.'' [333]

The OIG, too, has opined on this matter. In a September 2020 report titled, ''National Background Check Program for Long-Term Care Providers: Assessment of State Programs Concluded in 2019'' (OEI–07–20–00180), the OIG noted that patient abuse, patient neglect, and misappropriation of property have been detected as problems harmful to beneficiaries receiving long-term care. Somewhat akin to the previously mentioned June 2019 GAO report, the OIG stated that, per various studies, some nurse aides who were convicted of abuse, neglect, or theft had previous criminal convictions that could have been found through background checks of prospective employees.[334] The OIG added that such employee background checks can help protect long-term care beneficiaries.[335]

Our aforementioned concerns regarding problematic activity in the nursing home arena are not limited to patient abuse. Numerous recent cases have highlighted issues regarding fraud or improper billing among nursing home owners or operators. For instance:

- In April 2019, a jury found an owner of nursing homes and assisted living facilities in Florida guilty of 20 charges related to health care fraud. The United States Department of Justice (DOJ) noted that the owner's actions were part of the largest health care fraud scheme ever charged by the DOJ. It involved over $1.3 billion in fraudulent claims to Medicare and Medicaid for services that were not provided, were not medically necessary, or were procured through the payment of kickbacks.[336]
- In July 2021, a Virginia nursing home operator was sentenced to 2 years in prison for defrauding Medicaid after submitting more than $188,000 in false claims.[337]
- In March 2022, the DOJ settled a False Claims Act case with a Georgia nursing home for $400,000. The matter involved allegations that the nursing home deliberately billed Medicare for services that were not reasonable, necessary, and skilled.[338]
- A nursing home entity based in Georgia (which operates nursing homes across the country) agreed in May 2021 to pay $11.2 million to resolve allegations that it: (1) violated the False Claims Act by causing its nursing homes to bill the Medicare program for rehabilitation therapy services that were not reasonable, necessary or skilled; and (2) billed Medicare and Medicaid for substandard skilled nursing services.[339]
- In January 2020, a New York man pled guilty in federal court to embezzlement and tax offenses related to his operation of nursing homes in Connecticut.[340]
- Also in 2020, a Pennsylvania nursing home chain and its related companies agreed to pay more than $15 million to settle claims that the chain provided medically unnecessary rehabilitation therapy to residents in order to meet revenue goals, instead of clinical needs.[341]
- A California corporation and 27 affiliated nursing homes in the State agreed in July 2020 to resolve allegations that they violated the False Claims Act by submitting false claims to Medicare for rehabilitation therapy services that were not reasonable or necessary.[342]
- In June 2019, four Illinois nursing facilities and a physical therapy center agreed to pay $9.7 million to resolve civil allegations that they violated the False Claims Act by providing unnecessary services to increase Medicare payments.[343]
- A Tennessee-based nursing home chain agreed in February 2018 to pay more than $18 million in allowed claims to resolve a lawsuit brought by the DOJ and the State of Tennessee against them for billing the Medicare and Medicaid programs for substandard nursing home services.[344]

The disconcerting number of recent cases involving fraud and improper billing by nursing home owners and operators, as well as the OIG and GAO reports concerning patient abuse at the nursing homes these individuals oversee, requires, in our view, strengthened protections of the Medicare program and its nursing home beneficiaries. Indeed, CMS has an obligation to safeguard the integrity of

[329] *https://www.gao.gov/assets/gao-19-433.pdf.*

[330] Ibid.

[331] Ibid., 42.

[332] Ibid., 29.

[333] Ibid., 31–32.

[334] OEI–07–20–00180, p. 1. Such employee background checks are conducted pursuant to the National Background Check Program, enacted by legislation in 2010. This is a voluntary grant program for States to develop systems to conduct Federal and State background checks. See *https://www.bgcheckinfo.org/.*

[335] Ibid.

[336] *https://www.justice.gov/opa/pr/south-florida-health-care-facility-owner-convicted-role-largest-health-care-fraud-scheme-ever.*

[337] *https://www.justice.gov/usao-edva/pr/operator-residential-nursing-facility-sentenced-health-care-fraud.*

[338] *https://www.justice.gov/usao-ndga/pr/england-associates-lp-dba-new-london-health-center-pays-40000000-resolve-false-claims#:.*

[339] *https://www.justice.gov/opa/pr/savaseniorcare-llc-agrees-pay-112-million-resolve-false-claims-act-allegations.*

[340] *https://www.justice.gov/usao-ct/pr/nursing-home-operator-pleads-guilty-embezzlement-and-tax-offenses.*

[341] *https://www.justice.gov/usao-edpa/pr/pennsylvania-nursing-home-chain-pay-155-million-settle-false-claims-act-allegations.*

[342] *https://www.justice.gov/usao-cdca/pr/27-skilled-nursing-facilities-controlled-longwood-management-corp-pay-167-million.*

[343] *https://www.justice.gov/usao-ndil/pr/chicago-area-physical-therapy-center-and-4-nursing-facilities-pay-97-million-resolve.*

[344] *https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability.*

both the Trust Funds and the services that nursing home patients receive. Financial malfeasance and beneficiary abuse are unacceptable, and we believe that more closely scrutinizing the owners of nursing homes through our existing criminal background checks under § 424.518 can help detect potential criminal or abusive behavior at the nursing home before it begins. To illustrate, if a SNF owner is found through a fingerprint-based background review to have been convicted of battery, sexual assault, or other serious crime, this could raise significant concerns as to whether this conduct will be repeated during the owner's oversight or management of the facility. A SNF owner with an embezzlement conviction might be more inclined to divert the SNF's funds to his personal use (and away from monies otherwise intended for beneficiary care) than a different owner; he or she might also be more willing to tolerate malfeasance in the nursing home or to hire persons with criminal records. As two of the aforementioned OIG and GAO reports indicated with respect to nursing home employees, background reviews can prove helpful in screening individuals for possible problematic behavior. We, too, have found our fingerprint-based criminal background checks of great assistance in detecting felonious behavior by the owners of high-risk providers and suppliers.

Given the prevalence of recent unacceptable behavior by nursing home overseers and the OIG and GAO-documented instances of nursing home beneficiary abuse, we propose to revise § 424.518 to move initially enrolling SNFs into the high-level of categorical screening; revalidating SNFs would be subject to moderate risk-level screening. Requiring all SNF owners with 5 percent or greater ownership to submit fingerprints for a criminal background check would help us detect parties potentially posing a risk of fraud, waste, or abuse and, with this, the threat of patient abuse. In addition, our proposal, which we believe would assist in protecting Medicare Trust Fund dollars and beneficiaries, aligns with the Biden-Harris Administration's initiative to improve nursing home accountability.[345]

Previously, we referenced our authority under §§ 424.530(a)(3) and 424.535(a)(3) to deny or revoke enrollment based on a felony conviction within the previous 10 years; this includes a felony conviction against an owner of the provider or supplier. Notwithstanding our foregoing concerns about felonious activity by nursing home owners, we emphasize that our authority under §§ 424.530(a)(3) and 424.535(a)(3) is discretionary, meaning that we are not required to exercise it in every case.

g. DMEPOS Payment Denial Based on Violation of Supplier Standard

In comparison to most other provider and supplier types, DMEPOS suppliers have long presented to the Medicare program an elevated risk of fraud, waste, and abuse. In recognizing this threat, CMS over the years has established particularly stringent requirements that DMEPOS suppliers must meet in order to enroll and maintain enrollment in Medicare. These include, but are not limited to, requiring:

- The highest possible level of screening for initially enrolling DMEPOS suppliers, which includes site visits and the submission of fingerprints by each of the DMEPOS supplier's 5 percent or greater owners (§ 424.518(c)).
- The DMEPOS supplier's accreditation under § 424.58.
- Acquisition and maintenance of a surety bond under § 424.57(d).

The foregoing policies are meant to help ensure that Medicare enrolls and pays only those DMEPOS suppliers that are legitimate businesses capable of serving as reliable partners of the Medicare program. In furtherance of this aim, § 424.57(b) contains five separate conditions of payment that DMEPOS suppliers must meet to receive payment. These include, for example: (1) submission of a completed application to enroll in Medicare; and (2) furnishing a DMEPOS item only on or after the date CMS issued the supplier a billing number. Noncompliance with any DMEPOS condition of payment in § 424.57(b) can result in a revocation under § 424.57(e)(1). In addition, § 424.57(c) lists a number of enrollment standards with which DMEPOS suppliers must comply at all times. Should the supplier fail to meet any of the 30 standards, revocation under § 424.57(e)(1) is warranted.

One such enrollment standard, codified in § 424.57(c)(1)(ii)(A), provides that if the State requires licensure to furnish certain items or services, the DMEPOS supplier must be licensed to provide the item or service. We have encountered situations where an unlicensed DMEPOS supplier furnishes items for an extended period. The supplier then terminates its enrollment or CMS revokes the supplier's enrollment under § 424.57(e)(1) effective 30 days after the DMEPOS supplier is sent notice of the revocation per § 405.874. Tens of thousands of Medicare dollars were placed at great risk because the supplier was furnishing items and services while unlicensed up to the point of its termination of enrollment.

We see this as a potential vulnerability. Notwithstanding the aforementioned guardrails to stop DMEPOS fraud, initially enrolling DMEPOS suppliers remain at a high-risk screening designation, which we believe warrants heightened scrutiny to help ensure that all DMEPOS requirements are met. It would be inconsistent with our obligation to protect the Medicare Trust Funds to permit payment for items and services furnished while the supplier was non-compliant with the licensure requirements of § 424.57(c)(1)(ii)(A). Indeed, State licensure is a uniquely important program integrity protection because it helps ensure that the supplier meets certain minimum requirements of competency under State law to perform the services or furnish the items in question. Further, DMEPOS licensure, more than perhaps any other supplier standard in § 425.57(c), constitutes an additional level of vetting (that is, at the State level) that, in conjunction with our provider enrollment screening under 42 CFR part 424, subpart P and the provisions of § 424.57, is not necessarily duplicated with respect to requirements existing only at the Federal level. To illustrate, if a particular requirement in § 424.57(c) is also a prerequisite for State licensure, two reviews of the supplier's compliance will be performed: once at the State level and once at the Medicare enrollment level. Such multiple levels of verification that State licensure combined with Federal requirements can help ensure that the supplier is a bonafide and legitimate business.

Given the foregoing, we propose to add a new condition of payment in paragraph (b)(6) in § 424.57. Said condition would state that in order to receive payment for a furnished DMEPOS item, the supplier must have been in compliance with all conditions of payment in 424.57(b) as well as with § 424.57(c)(1)(ii)(A) at the time the item or service was provided. We note that section 1834(j)(1)(B)(ii)(I) of the Act requires, as a condition for obtaining a supplier number, that the DMEPOS supplier comply with all applicable State and Federal licensure and regulatory requirements. A DMEPOS supplier cannot receive payment unless it is enrolled and, as part of that, has a supplier number. Since compliance

[345] See *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

with licensure requirements is a specific statutory prerequisite for a DMEPOS supplier to be enrolled and because payment cannot occur without enrollment, we believe it logically follows that section 1834(j)(1)(B)(ii)(I) of the Act constitutes sufficient legal authority for our proposal.

K. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

On September 10, 2019, we published a final rule with comment period in the **Federal Register** titled ''Program Integrity Enhancements to the Provider Enrollment Process'' (84 FR 47794). Several provisions therein implemented section 1866(j)(5) of the Act. Section 1866(j)(5)(A) of the Act requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose any current or previous direct or indirect affiliation with a provider or supplier that—(1) has uncollected debt; (2) has been or is subject to a payment suspension under a Federal health care program; (3) has been or is excluded by the OIG from Medicare, Medicaid, and CHIP; or (4) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked. Under section 1866(j)(5)(B) of the Act, the Secretary may deny enrollment based on such an affiliation if the Secretary determines that the affiliation poses an undue risk of fraud, waste, or abuse.

The above-mentioned statutory requirements were implemented in §§ 424.502 and 424.519 with respect to Medicare enrollment and 42 CFR 455.101 and 455.107 for Medicaid and CHIP enrollment. The general purpose of the affiliation disclosure requirement is to help combat fraud, waste, and abuse by enabling CMS and the States to: (1) better track certain current and past relationships between and among different providers and suppliers; and (2) identify and take action on affiliations among providers and suppliers that pose an undue risk to Medicare, Medicaid, or CHIP.

In terms of the scope and timing of the disclosure requirement, section 1866(j)(5)(A) of the Act states that providers and suppliers submitting an application for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP must make the disclosures in a form and manner and at such time as determined by the Secretary. Based in part on concerns about the potential burden on the provider community in disclosing affiliations on every initial and revalidation application (and pursuant to the aforementioned statutory authorization regarding the form, manner, and timing for submitting disclosures), current regulations outline a ''phased in'' approach to implementing the disclosure requirements, pending further rulemaking. For Medicare enrollment, § 424.519(b) states that providers and suppliers must submit affiliation disclosures upon a CMS request. CMS will make these requests when it determines that an initially enrolling or revalidating provider or supplier may have at least one affiliation meeting certain criteria specified in the regulation. For Medicaid and CHIP enrollments, § 455.107(b) requires each State, in consultation with CMS, to select one of the following two options for implementing the disclosure requirement:

- Under Option #1, all providers that are not enrolled in Medicare but are initially enrolling in Medicaid or CHIP or revalidating their Medicaid or CHIP enrollment information must disclose their affiliations.
- Under Option #2, providers that are not enrolled in Medicare but are initially enrolling in Medicaid or CHIP or revalidating their Medicaid or CHIP enrollment information must disclose their affiliations only upon request from the State. (The State will make the request when, in consultation with CMS, it has determined that the initially enrolling or revalidating provider may have at least one affiliation meeting certain criteria specified in the regulation.)

The central operational difference between these two Medicaid and CHIP options is that the first requires disclosures with every initial and revalidation application (assuming the provider is not Medicare-enrolled) while the second requires disclosures with the applications only upon the State's request. On a broader level, the second option permits the State to undertake a slower, phased-in implementation. That is, rather than require all initially and revalidating non-Medicare-enrolled providers to report their affiliations, the State may, in consultation with CMS, adopt the more targeted approach of requiring disclosures upon request, mirroring the approach adopted in § 424.519(b) for Medicare. We believe that affording options gives States greater flexibility in implementing the affiliation disclosure requirements.

Despite this goal, existing § 455.107(b)(1)(ii) holds that the State cannot change options once its selection has been made. Our concern at the time of promulgating § 455.107(b) was that switching options after one of them is implemented could lead to logistical and administrative complications and, perhaps, confusion in the provider community as to what the State requires. However, after consultations with the States and after analyzing data regarding the submission of affiliation disclosures to date, we do not believe § 455.107(b)(1)(ii) needs be so restrictive. A number of States are seeking greater discretion in their operationalization of § 455.107(b). They believe that requiring the State to continue implementing its selected option without change could hinder its operations and/or its program integrity efforts if that option is proving impracticable or inefficient for that particular State.

We share these States' concerns and agree that increased flexibility is warranted. To this end, we are proposing to revise § 455.107(b)(1)(ii) to read that a State may, in consultation with CMS, change its selection under § 455.107(b) (after it has been made) from § 455.107(b)(2)(ii) to § 455.107(b)(2)(i). However, we would not permit a change from § 455.107(b)(2)(i) to § 455.107(b)(2)(ii). This is because the former option more thoroughly implements section 1866(j)(5)(A) of the Act, and thus, furnishes greater program integrity protections by requiring all enrolling or revalidating providers to disclose affiliations while § 455.107(b)(2)(ii) requires disclosure in more limited circumstances. As noted in the previously mentioned September 10, 2019 final rule with comment period: ''Section 1866(j)(5) of the Act requires every provider and supplier (regardless of the relative risk they may pose) to disclose affiliations upon initial enrollment and revalidation. All States that choose the second option will therefore eventually be required to collect affiliation disclosures from their providers upon the submission of each initial and revalidation application'' (84 FR 47816). Consistent with the phased-in approach adopted in that rule and in the interest of protecting the Medicaid program and CHIP from fraud, waste, and abuse, we believe it is appropriate to allow States the flexibility to move from the second, more limited implementation option to the first, more robust option. Conversely, we do not believe that States that chose the full implementation option in § 455.107(b)(2)(ii) should be permitted to scale back their approach by changing their selection to the more limited ''upon request'' option.

L. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

In the CY 2021 PFS final rule and CY 2022 PFS final rule, we finalized policies for the EPCS requirement specified in section 2003 of the SUPPORT Act (Pub. L. 115–271, October 24, 2018). We refer readers to 86 FR 65361 through 65370 for the complete details of the statutory requirements and those finalized policies. Specifically, in the CY 2022 PFS final rule, we finalized multiple proposals related to EPCS. First, we finalized our proposal to extend the date of compliance actions to no earlier than January 1, 2023, and for prescribers writing Part D controlled substances prescriptions for beneficiaries in long-term care (LTC) facilities, we extended the date on or after which we will pursue compliance actions from January 1, 2022 to January 1, 2025 (86 FR 65364 and 65365). Second, we finalized our proposal to require prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366). Third, we finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369): (1) we amended § 423.160(a)(5) by adding paragraph (a)(5)(i), which is the exception listed in section 1860D–4(e)(7)(B)(i) of the Act, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity; (2) we amended § 423.160(a)(5) by adding paragraph (a)(5)(ii), which created an exception for prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using prescription drug event (PDE) claims data as of December 31st of the preceding year; (3) we amended § 423.160(a)(5) by adding paragraph (a)(5)(iii) to create an exception for prescribers located in the geographic area of an emergency or disaster declared by a Federal, State or local government entity; and (4) we amended § 423.160(a)(5) by adding paragraph (a)(5)(iv) to create an exception for prescribers who have received a CMS-approved waiver because the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control, respectively. We did not adopt exemptions for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits, or for prescribers issuing prescriptions for individuals enrolled in hospice. Finally, we finalized our proposal to limit compliance actions with respect to compliance from January 1, 2023 through December 31, 2023, to a non-compliance letter sent to prescribers that we believe are violating the EPCS requirement (86 FR 65370).

2. Evaluation of Compliance

In the CY 2022 PFS final rule, we discussed the EPCS policy, exceptions, and a compliance threshold. Specifically, we stated that starting in CY 2023, CMS would begin initial EPCS compliance actions (86 FR 65363). We believe it is important to provide a general timeline that describes the general process by which prescriber compliance will be evaluated. Previously, we stated that some exceptions would be evaluated on the basis of Prescription Drug Event (PDE) data from the preceding year as opposed to the evaluated year. We recognize that prescriber practices may change from year to year and believe it is inconsistent to evaluate exceptions and compliance on the basis of PDE data from the preceding year as opposed to the year under evaluation. To that end, we aim to use PDE data from the evaluated year (that is, the current year) as soon as it becomes available to ensure that the data is relevant to the prescriber's practices in the evaluated year. For example, evaluation of CY 2023 prescriber practices will be based on CY 2023 PDE data, though the evaluation will not begin until late CY 2024 and will be based on the PDE data used in the Part D Payment Reconciliation for CY 2023. Following the PDE availability and our evaluation for exceptions and compliance, CMS will begin addressing prescriber noncompliance by issuing non-compliance letters as previously described in the CY 2022 PFS final rule (86 FR 65370).

Additionally, in this proposed rule, we propose to extend the existing non-compliance action of sending letters to non-compliant prescribers for the EPCS program implementation year (January 1, 2023 through December 31, 2023) to the following year (January 1, 2024 through December 31, 2024). We are also proposing a change to the data source used to identify the geographic location of prescribers to inform the recognized emergency exception. Starting in CY 2025, CMS plans to begin increasing the severity of penalties for noncompliant prescribers, from issuance of non-compliance letters to other penalties, using the same timeline established here. Therefore, we are seeking further public comment on potential penalties for noncompliant prescribers in section III.L.4. of this proposed rule.

3. Proposed Changes to Exceptions

a. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

In the CY 2022 PFS final rule we finalized our proposal to amend § 423.160(a)(5) by adding § 423.160(a)(5)(ii), which created an exception for prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using PDE claims data as of December 31st of the preceding year, so that these prescribers are not required to meet the EPCS requirement. We referred to this exception as one for small prescribers. For a complete discussion of this topic please see the CY 2022 PFS final rule (86 FR 65366 and 65367). We note that we intended to implement this proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within this exception. We stated CMS will use the previous year's data to determine whether the prescriber falls under this exception for the year-in-question.

We are now proposing to modify the exception to better align the timeframes of data used to evaluate each exception. We note that, other than the small prescriber exception, every exception described in the CY 2022 PFS final rule is evaluated based on data from the same year to which the exception is applied. For instance, in the case of a recognized emergency, an exception would be granted during the period of time in the year in which the emergency took place, and the emergency would not be considered for an exception in the following year's compliance evaluation, except to the extent that the emergency continued into the following year. Similarly, for purposes of § 423.160(a)(5)(ii), we believe that it is consistent to consider the prescriptions issued during the evaluation period, rather than the previous year, in case there are year-over-year changes. In this manner, we believe this proposal is a more consistent approach than the existing requirement to utilize claims data from the prior year to assess whether a prescriber issues 100 or fewer Part D controlled substance prescriptions.

Therefore, we are proposing to change the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines

whether a prescriber qualifies for an exception based on the number of Part D controlled substance claims. To effect this change, we are proposing to modify the exception at § 423.160(a)(5)(ii), which states, ''Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data as of December 31st of the *preceding* year,'' by changing ''CMS claims data as of December 31st of the preceding year'' to ''CMS claims data with dates of service as of December 31st of the current year.'' If finalized, this proposal would become effective for CY 2023 and for subsequent years. Thus, for CY 2023 EPCS compliance, the small prescriber exception would be assessed using CY 2023 PDE data based on our proposed change. Additionally, a prescriber's compliance status would be evaluated based on PDE data with a 'Date of Service' within the evaluated calendar year using PDE data, which Part D sponsors must submit by mid-way through the following year. For an example of how we propose this to work in practice, consider the following illustration. Prescriber A had fewer than 100 Medicare Part D controlled substances prescriptions in CY 2022, and therefore, was excepted from EPCS compliance for CY 2022. During the first quarter of CY 2023, she issues 85 Part D controlled substance prescriptions. After Prescriber A crosses the threshold of more than 100 Part D controlled substance prescriptions, she must reach the compliance threshold of electronically prescribing at least 70 percent of all her prescribed Part D Schedule II, III, IV, and V controlled substances in CY 2023. If she does not utilize EPCS for at least 70 percent of Part D controlled substance prescriptions in CY 2023, including those prescribed prior to reaching the 100 Part D controlled substances prescriptions threshold, she would be subject to a compliance action based on failing to meet the requirement at § 423.160(a)(5), unless another exception applied. PDEs with a Date of Service between January 1, 2023 to December 31, 2023 with a submission date on or before the PDE submission deadline for 2023 (that is, June 28, 2024) would be included in the compliance analysis.

If our proposal is finalized, neither CMS nor an individual prescriber will be able to determine until after the evaluation year whether or not the individual prescriber qualifies as a ''small prescriber'' for purposes of § 423.160(a)(5)(ii), unless the prescriber tracks the number of Medicare Part D controlled substance prescriptions the prescriber issues during the evaluation year. This is in comparison to our existing policy, where CMS would not determine if prescribers qualify as a ''small prescriber'' until the middle of the evaluation year when the PDE data from the prior year becomes available. Despite the delay in identifying which prescribers qualify for the small prescriber exception, we believe this proposal will better identify small prescribers for purposes of EPCS compliance and simplify the program by aligning the time periods of the exceptions. We also believe that prescribers will be able to more clearly understand their Medicare Part D controlled substance prescribing patterns throughout the first two years of the EPCS program, where the only action for non-compliance is a letter.

We seek comment on our proposal to modify the exception at § 423.160(a)(5)(ii) and on the possibility that prescribers would avoid prescribing controlled substances to Medicare beneficiaries, particularly where they are approaching the 100 Part D controlled substances prescriptions threshold late in a calendar year, in order to remain a small prescriber.

Additionally, recognizing some prescribers are expecting CMS to use the CY 2022 PDE to assess whether the exception at § 423.160(a)(5)(ii) applies for purposes of CY 2023 EPCS compliance, we seek comment on an alternative for the CY 2023 year only. In the alternative, we would recognize a prescriber as a small prescriber for purposes of the exception at § 423.160(a)(5)(ii) if the prescriber had fewer than 100 Part D controlled substances prescriptions in 2022 or fewer than 100 Part D controlled substances prescriptions in 2023. We did not propose this option because we thought it would be simpler to have a single set of exceptions for the program versus different rules for different years. Additionally, we believed the risk to prescribers who may change their small prescriber status would be low as the action for non-compliance for CY 2023 is a letter.

b. Cases of Recognized Emergencies

In the CY 2022 PFS final rule (86 FR 65367 and 65368), we finalized our proposal to adopt an exception at § 423.160(a)(5)(iii), for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. We stated that to qualify for this exception, this circumstance will have to arise from an emergency or disaster declared by a Federal, State, or local government entity. We finalized our proposal to determine whether a prescriber qualifies for this exception based on whether the prescriber's National Council for Prescription Drug Programs (NCPDP) Pharmacy Database address is located in the geographic area of an emergency or disaster declared by a Federal, State or local government entity, which is reflected in the text of § 423.160(a)(5)(iii). Since, as stated in the CY 2022 PFS proposed and final rules, we had intended this exception to avoid unduly burdening prescribers during difficult situations, CMS would like to again clarify that this exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring.

We have determined that the NCPDP Pharmacy Database contains pharmacy addresses as opposed to prescriber addresses. Because it is likely that the address of a prescriber differs from that of the pharmacy where a prescription is filled, and the prescriber might be located at an address within an emergency or disaster area when the pharmacy is not, we believe the NCPDP database may not always be an appropriate data source to inform the exception based on emergencies such as natural disasters, pandemics, or similar situations where there is an environmental hazard. It is our intention that the EPCS exception apply to where the prescriber is located, not where the pharmacy is located, to the extent that the locations differ. We believe the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) would have the most current address information for prescribers who are enrolled in Medicare. Additionally, this is the data source that the Quality Payment Program's Merit-based Incentive Payment System (MIPS) uses to determine if a MIPS eligible clinician is located in an area that has been affected by extreme and uncontrollable circumstances (82 FR 53895 through 53900). Therefore, for prescribers who have an address in PECOS, we propose to use the PECOS address instead of the of the NCPDP Pharmacy Database address to determine whether the exception at § 423.160(a)(5)(iii) is applicable. We are concerned however, that not all prescribers would be enrolled in Medicare and therefore their addresses would not be in PECOS. In situations where prescribers do not have a PECOS address, we propose to use the prescriber address in the National Plan and Provider Enumeration System

(NPPES) data. We propose to revise the text of § 423.160(a)(5)(iii) accordingly. Additionally, we seek public comment on whether using NPPES, NCPDP, or some other database is appropriate when there is no prescriber address in PECOS.

We also seek comment on an alternative of using NPPES as the source of addresses for all prescribers. We believe this data may have information for all prescribers, but that providers may not update their address as often as they do in PECOS. Finally, we seek comment on other potential data sources that could be used to verify a prescriber's address for purposes of § 423.160(a)(5)(iii).

4. Penalties

Section 1860D–4(e)(7)(D) of the Act gives the Secretary the authority to enforce and specify appropriate penalties for non-compliance with the EPCS requirement through rulemaking. In the CY 2022 PFS proposed and final rules, we sought feedback from interested parties on whether CMS should impose penalties and if so, what penalties should be imposed. We are continuing to examine State EPCS requirements and their accompanying penalties. However, because these requirements have only been recently implemented and most States do not have penalties for failing to adopt EPCS, we have not been able to evaluate what type of penalties have been effective to enforce State mandates.

In our ongoing implementation of the EPCS requirement, we continue to seek input to ensure that we do not place too much of a burden on prescribers, as we do not want this requirement to have an unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries, where appropriate, should they not have EPCS set-up. We continue to need additional time to gather more feedback from interested parties on the most effective and most appropriate type of penalties. In the CY 2022 PFS final rule, we finalized our proposal to limit CY 2023 compliance actions to a non-compliance letter sent to prescribers that are violating the EPCS requirement.

a. Timing for Issuing Non-Compliance Letters

In this proposed rule, we are proposing to adjust the period of time during which CMS will issue non-compliance letters. With respect to the period of time during which CMS non-compliance actions will consist of sending letters to prescribers that we believe are violating EPCS requirements, we are proposing to extend the existing compliance action of sending letters to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024 through December 31, 2024). If adopted, CMS compliance actions will consist of CMS sending letters to prescribers who we believe are violating the EPCS requirement between January 1, 2023 and December 31, 2024. The content of the letters would remain unchanged. These letters would consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. We are seeking public comment on this proposal.

b. Request for Information Relating to Potential Future EPCS Penalties

Consistent with the CY 2022 PFS final rule, we continue to be interested in identifying additional meaningful penalties to enforce the EPCS requirement. Therefore, we are seeking public comment on additional penalties that CMS may impose to enforce the EPCS requirement. Such penalties would go into effect no sooner than January 1, 2025 if we extend the timeframe during which we will issue non-compliance letters, as we have proposed. There are a range of options that we are exploring, and we believe feedback from interested parties will help us to develop meaningful and appropriate penalties in the future. We are currently considering the following non-exhaustive list of penalties for non-compliant prescribers:

- *Requiring a non-compliant prescriber to enter into a corrective action plan, which would require the non-compliant prescriber to comply with the EPCS requirement within 2 years prior to applying other potential actions outlined in this section.* Some commenters previously recommended corrective action plans be used prior to applying penalties. CMS seeks comment on what types of elements and actions should be in a corrective action plan that encourages use of EPCS without being overly burdensome. We seek comment on whether a corrective action plan would be perceived as overly burdensome to non-compliant prescribers and whether a 2-year timeframe is reasonable and appropriate. We also seek comment on whether a corrective action plan should be applied prior to other potential actions described in this section or whether a corrective action plan should be established in parallel with other actions.
- *Posting a non-compliant prescriber's name on the CMS website and identifying the prescriber as non-compliant.* CMS seeks comment on whether this action would be sufficient to persuade prescribers to alter their behavior. We seek comment on whether beneficiaries and interested parties would be able to utilize this information to their benefit.
- *Public reporting of EPCS compliance status, including that a prescriber is non-compliant, on the Care Compare website.* CMS seeks comment on whether this action would be sufficient to persuade prescribers to alter their behavior. We seek comment on whether beneficiaries and interested parties would be able to utilize this information to their benefit.
- *Referral of non-compliant prescribers to the DEA to support potential investigations.* We request comment on an option under which CMS would provide the list of the EPCS non-compliant prescribers to the DEA to supplement current investigations and activities. The DEA would have the sole authority to use the information as permitted under DEA regulations and applicable law. CMS seeks comment on whether interested parties envision this as being an effective option for enforcing EPCS compliance. We seek comment on whether interested parties have any recommendations that increase the effectiveness of this potential option. We seek comment on whether CMS should consider the duration of EPCS non-compliance prior to referring the prescriber to the DEA and whether a corrective action plan should be considered prior to referring the prescriber.
- *Sharing the list of EPCS non-compliant prescribers with the States.* CMS seeks comment on whether interested parties believe sharing the list of EPCS non-compliant prescribers with State level entities would be beneficial to the enforcement of EPCS compliance. We seek comment on how States may use this information to further assist CMS' efforts to enforce the EPCS requirement.
- *Referral for potential fraud, waste and abuse review.* CMS seeks comment on whether it should refer Medicare enrolled prescribers who consistently do not comply with the EPCS requirement for a fraud, waste, and abuse investigation to be undertaken by CMS. Multiple years of non-compliance may be a significant enough issue to consider a review for potential fraud, waste and abuse investigation. We seek

comment on whether we should consider the duration of EPCS non-compliance when considering such a referral and whether other factors should also warrant an internal referral.

- *For penalties involving referral of non-compliant prescribers to the DEA and other entities, our intent is to supplement the current activities of these entities rather than to create new regulatory actions.* We envision that information sent to these entities would be for use at the discretion of the recipient. We are interested to know if interested parties believe there is any utility in referring non-complaint prescribers to the DEA, other CMS internal centers, or the States. If so, we seek comment on in what manner this data can be used to supplement EPCS compliance enforcement.

Any penalty involving the posting of compliance status on CMS websites would be done in a manner consistent with relevant statutory authority. For instance, we note that any potential posting of compliance information on the Care Compare website would have to be done consistent with statutory authority potentially including, but not necessarily limited to, authority in section 10331 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (March 23, 2010); section 1848(q)(9) of the Act; and regulatory authority at 42 CFR 414.1395. Section 10331(a)(2)(G) of the ACA states that to the extent scientifically sound measures that are developed consistent with the requirements of this section are available, such information, to the extent practicable, shall include other information as determined appropriate by the Secretary.

As we stated above and in the CY 2022 PFS final rule, we believe there are multiple advantages to the electronic prescribing of controlled substances: improved workflow efficiencies; deterring and detecting prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions; and providing more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. We also stated that EPCS may reduce the burden on prescribers who need to coordinate and manage paper prescriptions among staff, patients, facilities, other care sites, and pharmacies. For these and potentially other reasons, we believe the EPCS compliance efforts directly relate to prescriber performance and quality, and related patient experience, as contemplated by section 10331(a)(2) of the ACA. We are seeking comment from interested parties on these and other options they may suggest for penalties to enforce EPCS compliance. We are interested in public comments that address:

- Whether any penalties described above are appropriate as compliance actions without being overly burdensome;
- Whether interested parties believe these penalties will be effective at increasing prescriber compliance;
- Whether penalties should be phased in over time and, if so, after what date CMS should first impose them;
- The utility of posting compliance information to the CMS website or more specifically to the Care Compare website; and
- Whether there are any other penalties not mentioned here which CMS should consider to enforce EPCS compliance.
- How best CMS can enforce EPCS compliance by prescribers who are not billing under Medicare but who prescribe controlled substances to Medicare Part D beneficiaries.

M. Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services is made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments at § 414.610(c)(5)(i) are: (1) a 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments at sections 1834(l)(12)(A) and (13)(A) of the Act and § 414.610 are: (1) a 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Section 50203(a)(1) and (2) of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018) includes an extension of the temporary add-on payments through December 31, 2022.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirements for the Ground Ambulance Providers and Suppliers To Submit Cost and Other Information Background

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers (ground ambulance organizations) to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Section 1834(l)(17)(B)(i) of the Act required the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act required that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for

a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Section 311 of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103) amended section 1834(l)(17)(F)(i) to delay the deadline for MedPAC to submit its report to Congress on the ground ambulance data collection system study until the second June 15th following the date the Secretary transmits data for the first representative sample of ground ambulance organizations. Section 1834(l)(17)(I) of the Act states that the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.) does not apply to the collection of information required under section 1834(l)(17) of the Act.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance organizations at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. In the CY 2020 PFS final rule (84 FR 62863 through 629897), we finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. This instrument includes the specific questions that will be asked of ground ambulance organizations about the total service volume, costs, and revenue associated with a provider or supplier's entire ground ambulance organization in such a way that MedPAC could use to calculate an average cost per ground ambulance transport. We refer the reader to our CY 2020 PFS final rule (84 FR 62863 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

In the CY 2022 PFS final rule (86 FR 65306 through 65317), we finalized a number of updates to the Medicare Ground Ambulance Data Collection System, including: (1) a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in year 3; (2) aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and the data collected will be publicly available beginning in 2024; and (3) revisions to the Medicare Ground Ambulance Data Collection Instrument that include better accounting for labor hours across different categories of personnel and better distinguishing between accrual and cost basis accounting methodologies. We refer the reader to our CY 2022 PFS final rule (86 FR 65306–65317) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

3. Proposed Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2020 PFS final rule (84 FR 62867), the Medicare Ground Ambulance Data Collection Instrument uses screening questions and skip patterns so that it is applicable to all ground ambulance organizations regardless of their size, scope of operations and services offered, and structure. We stated that we believe this approach is easier to navigate and less time consuming to complete than a cost report template or instrument and that it minimizes respondent burden by directing ground ambulance organizations to only view and respond to questions that apply to their specific type of organization, all while still collecting the information required in sections 1834(l)(17)(A) of the Act.

The CY 2020 PFS final rule provided a detailed overview of the elements of the data collection instrument, including questions to collect information on costs, revenues, utilization (which CMS defines for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations. Table 73 includes a high-level summary of the 13 sections of the Medicare Ground Ambulance Data Collection Instrument.

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TABLE 73: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
General Survey Instructions (1)	Information on background and motivation for data collection, instructions for navigating the instrument, and links for questions and other resources.
Ground Ambulance Organization Characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground Ambulance Service Volume (5) and Service Mix (6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Hours and costs associated with EMTs, administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; annual cost of ownership, insurance, maintenance, and utilities.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual cost of ownership; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

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As described in the CY 2022 PFS final rule (86 FR 65307), we made several changes to the instrument instructions and questions to improve clarity and reduce burden for respondents. A printable version of the current instrument instructions and questions is available in English and Spanish on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*.

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via four primary channels. First, we receive email and other written communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers to commonly asked questions. This document is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*. Through review of questions and feedback, we have identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document. Second, we answer questions live from interested parties during webinars, dedicated question and answer sessions, and other educational sessions. As with the emailed questions described above, live question and answer exchanges sometimes identify opportunities for clarifying instrument language. Third, our contractor asked a small number of ground ambulance organizations to test the most recent version of the Medicare Ground Ambulance Data Collection Instrument. Feedback from this preliminary testing effort was helpful to identify some additional opportunities for clarification. Fourth, we continue to identify opportunities to clarify instructions and correct a small number of typos as we work to develop the web-based, programmed version of the Medicare Ground Ambulance Data Collection Instrument.

Based on information that we received via the four sources described above, we are proposing the following further changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both. We group our proposed changes and clarifications into four broad categories:

- Editorial changes for clarity and consistency.
- Updates to reflect the web-based system.
- Clarifications responding to feedback from questions from interested parties and testing.
- Typos and Technical Corrections.

A draft of the updated instrument that includes all of the CY 2023 proposed changes to review and provide

comments on is posted on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

a. Editorial Changes for Clarity and Consistency

We are proposing 14 editorial changes to improve the clarity of instrument instructions and questions. We do not believe these changes substantively affect the meaning of any instruction or question.

The first three proposed changes would apply throughout the entire Medicare Ground Ambulance Data Collection Instrument. Specifically, we are proposing to:

- Use the past tense to refer to data collected during selected ground ambulance organizations' continuous 12-month data collection periods throughout the instrument. All organizations are currently required to complete their data collection prior to reporting the data. Using the present tense may be confusion by implying organizations should report data beyond their 12-month data collection period.
- Consistently refer to ''ground ambulance'' rather than only ''ambulance'' throughout the instrument to clarify that the scope of the Medicare Ground Ambulance Data Collection System (GADCS) is limited to ground ambulance operations and not air ambulance operations.
- Edit sentences written in the passive voice to the active voice for editorial consistency.

The fourth and fifth proposed changes focus on Section 1 (General Survey Instructions) in the instrument as we are proposing to:

- Refer to organizations' ''continuous 12-month data collection period'' rather than just ''12-month data collection period'' throughout the instrument. We believe this will help remind organizations that their data collection period must cover a continuous, 12-month period.
- Align the description of how organizations must provide their data collection start date prior to data reporting in Section 1 (General Survey Instructions) with the process codified at § 414.626(b)(1).

The remainder of proposed changes in this category focus on editorial changes to specific instrument questions or instructions in Sections 2 (Organizational Characteristics) through Section 6 (Service Mix). Specifically, we are proposing to:

- Edit response Option d in Section 2, Question 9 from ''Another health care organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services),'' to ''Other health care delivery operations such as a clinic or urgent care center (excluding hospitals, skilled nursing facilities, or other Medicare provider of services in Option c).'' In a previous clarification, we reworded Section 2, Question 9 from ''Does your ground ambulance operation share any operational costs, such as building space or personnel, with one of the following?'' to ''Does your organization provide any of the following services or operations (select all that apply)?'' Given the change in the structure of the question asking about types of services/operations as opposed to types of organizations, we are proposing to reword one answer option to better reflect the question.
- Clarify Section 4 (Emergency Response Time), Question 4b, which asks whether the organization is penalized if it exceeds response time targets, to focus specifically on monetary penalties. We are concerned that the current phrasing is too subjective and will be difficult for respondents to answer.
- Clarify that the definition of ''total response'' in the Section 5 (Ground Ambulance Service Volume) instructions and Section 5, Question 1 applies to ''emergency responses'' rather than ''EMS responses.'' In some organizations, the initial responders to a call for service may not be EMS responders.
- Clarify that estimates of the share of responses that are joint with another organization are acceptable in Section 5, Question 3c, to better align with Section 5, Question 3a where estimates are explicitly permitted.
- Specify in Sections 5 and 6 (Service Mix) and elsewhere in the Medicare Ground Ambulance Data Collection Instrument when questions ask for information on ''ground ambulance transports'' rather than just ''transports'' to avoid confusion with services that may colloquially be referred to as transports but that do not meet the definition of a ''ground ambulance transport'' in the instrument, which is defined as ''the use of a fully staffed and equipped ground ambulance responding to a request for service to provide a medically necessary transport (based on the rules relevant to the applicable payer).''

The 11th and 12th proposed changes apply to Section 7 (Labor Costs) where we are proposing to:

- Standardize the example staff categories listed under ''other medical staff'' across all Section 7 tables. Currently, the first table in Section 7 lists ''respiratory therapist'' among example staff categories while none of the subsequent tables do. We are proposing to remove ''respiratory therapist'' as an example from the first table in Section 7 for consistency and brevity. However, respiratory therapists should continue to be included in this category, along with all other medical staff, even if they are not specifically cited as an example.
- Add a reminder (''do not include medical directors'') in Section 7.3 (Volunteer Labor), Question 3 on administrative/facility volunteer hours to ensure respondents do not include medical directors in this category (medical director hours are reported separately).

The 13th proposed change applies to Section 9 (Vehicle Costs) as we are proposing to:

- Define ''Quick Response Vehicle'' alongside the acronym (QRV) throughout the instrument and particular in Section 9 (Vehicle Costs). The current Section 9 instructions sometimes refer to ''QRV'' without elaboration. We believe this may be confusing to some ground ambulance organizations.

The 14th and final proposed change in this category relates to Section 13 (Revenue). Specifically, we are proposing to:

- Edit the warning that applies to organizations operating both ground and air ambulances in Section 13 to clarify that air ambulance revenue should not be included in Section 13 except in the organization's response to Section 13, Question 1. This question explicitly asks organizations to report on revenue across their entire organization, including revenue related to services other than ground ambulance services, and so the current warning may seem to be contradictory.

We invite comments on these 14 proposed editorial changes for clarity and consistency.

b. Updates To Reflect the Web-Based System

We are in the process of developing the web-based GADCS portal and programmed instrument that ground ambulance organizations will use to report data. The printable instrument noted several cases where the ultimate instrument functionality and wording hinges on the specifications and implementation of the GADCS portal and programmed instrument, for example around account creation, programmed skip logic, and pop-up warnings.

We are proposing 13 changes to the printable instrument so that it better matches our current plans and

expectations for the programmed instrument. We believe these changes will help ground ambulance organizations referencing the printable instrument understand how the data they have collected should be entered in the programmed instrument on the GADCS portal. We are proposing to:

- Update the brief description of the programmed instrument's functionality in Section 1.

We propose the specific text: ''Your organization must report the required information prior to [INSERT DATE], which is 5 months after the end of its data collection period. You can enter the required information over multiple sittings. The system will save your responses after every screen, or whenever you hit the ''Save'' button at the bottom of your screen. When you log in again later, you can pick up where you left off. After you enter all required information, a Certifier at your organization will review the entire response and either request changes or certify the information. [Note: This instruction will be updated to reflect the capabilities of the programmed instrument.]'' This description provides readers of the printable instrument a clearer sense of the functionality they should expect from the programmed instrument.

- Add specific pop-up window text from Section 2, Question 1 in the programmed instrument to the printable instrument. Section 2, Question 1 confirms that the ground ambulance organization billed Medicare for ground ambulance services during its continuous, 12-month data collection period. A response of ''no'' effectively ends the organization's reporting requirement under GADCS. As a result, the programmed instrument includes pop-up warnings asking the respondent to confirm that they did not bill Medicare for ground ambulance services. We believe describing the pop-up boxes as programming notes in the printable instrument will help organizations no longer providing ground ambulance organizations understand how they will progress through the GADCS.
- Edit the printable instrument to refer to ''your organization's data collection period'' in rather than ''calendar year 202X [or fill fiscal year as appropriate]'' throughout the document. Given CMS' approach to collecting data collection period start dates and contact information from organizations within 30 days of notification, we expect to know the data collection period start date ahead of the organization entering the web-based GADCS. We believe it will be clearer for organizations if the question text refers consistently to the organization's data collection period.
- Move Section 7.2, Question 4 (''Does your organization contract with a medical director, rather than employing them directly?'') to earlier in Section 7, immediately following Section 7, Question 1, to become Section 7, Question 2. The existing Section 7, Question 2 item (asking about staff categories not used by the organization) would be renumbered as Section 7, Question 3. With the current flow of Section 7 in the printable instrument, organizations contracting with a medical director must confusingly answer a question on why they do not employ a medical director *before* they report that they contract with one. Asking whether the organization contracts with a medical director earlier in Section 7 enables the programmed instrument to better adapt later questions in Section 7 related to medical directors. For example, organizations indicating earlier in Section 7 that they contract with a medical director will not need to be asked why they do not employ a medical director.
- Clarify the instructions for Section 8.1 (Facility Information) Question 1, Section 9.1 (Ground Ambulance Vehicle Costs), Questions 1 and 2, and Section 9.2 (Other Vehicle Costs (Non-Ambulance)), Questions 1 and 2 so that they note the number of facilities and vehicles that users report as answers to these questions will adjust the number of rows that they subsequently see in Section 8.2 (Annual Lease, Mortgage, and Other Costs of Ownership for Facilities), Section 9.1, and Section 9.2 tables, respectively. We believe this clarification will help users understand the linkages between these initial questions and the later tables that they need to fill out. This clarification may also help users appreciate that changing earlier answers to these initial questions will have ramifications for the tables that follow, including the potential addition or deletion of rows.
- Allow organizations to enter information by hand or via an uploaded file for the facility-level tables in Section 8.1 and for the vehicle-level tables in Section 9.1 and Section 9.2. These tables require organizations to report on the characteristics and expenses related to individual facilities and vehicles. Ground ambulance organizations with many facilities and/or vehicles may find it burdensome to enter information on each facility and vehicle individually in the web-based GADCS. Other organizations may find it easier or preferable to enter information by hand. Organizations choosing to import responses for these three tables would use Microsoft Excel templates with the same structure as the tables in the web-based instrument. Organizations would download these templates prior to or while reporting information to the GADCS, complete the template, and then import the completed template into the GADCS. The GADCS would validate completed templates and request modifications (if necessary) prior to accepting completed templates. Organizations importing responses for these tables would have an opportunity to review their responses before continuing to later Section 8 and/or Section 9 questions. This proposed change would require clarification in the Section 8 and Section 9 instructions to describe the two alternative data entry approaches. The revised instructions would stress that the use of the import templates is optional and that the exact same information is required regardless of whether information is entered by hand or via the template. We believe offering the option to import responses to these tables will substantially reduce response burden particularly for larger ground ambulance organizations with many facilities and/or vehicles.

The remaining proposed changes in this category (changes 6–12) aim to harmonize and clarify programming notes throughout the instrument related to ground ambulance organizations that also provide other services (for example, fire departments, or ''shared services'' as we describe them in the instrument). The programming notes in the printable instrument are meant to provide context to readers on the ultimate functionality of the programmed instrument within the constraints of a static document. Some of these programming notes have been broadened and updated since the initial version of the printable instrument while others have not. We believe some ground ambulance organizations may want to respond to questions as if they were shared services, even if they do not meet the specific programming notes laid out in the printable instrument. Broadly, we are proposing to expand or remove programming notes restricting certain responses for follow-up questions for shared services. We believe this will provide respondents with more flexibility to respond to questions in a way that best matches their characteristics, services, and organizational structure.

Specifically, for changes to programming notes, we are proposing to:

• Edit the Section 2, Question 9 note to read: '[Note: For the remainder of the data collection instrument, instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that answer Section 2, Question 7= ''a'' or ''b'' AND Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b. To streamline the skip logic, the answers to these questions are referred to as ''Public Safety = Yes'' for the remainder of the document.]'

• Clarify the definition of ''total responses'' in the Section 5 (Service Volume) instructions and Question 1 which currently reads: ' '[If Section 2, Question 7 is ''a'' also display] ''Include emergency responses that did not involve a ground ambulance, such as those involving only fire trucks and/or other fire/rescue vehicles;'' [if ''b''] ''Include emergency responses that did not involve a ground ambulance, such as those involving only police cars and/or other public safety vehicles.'' ' These instructions do not account for those who indicated public safety services in Section 2, Question 9. We propose to use the new ''public safety'' definition and to decrease repetitiveness for those with both fire and other public safety services: ''[If Public Safety=Yes] Include emergency responses that did not involve a ground ambulance, such as those involving only fire trucks, other fire/rescue vehicles, police cars and/or other public safety vehicles.''

• Edit programming notes throughout Section 7 (Labor Costs) instructions to refer to ''If Public Safety=Yes'' rather than ''if appropriate for shared services.''

• Make the skip logic more precise and consistent throughout Section 7.1 by changing ''[Include only if relevant based on responses to Section 7, Question 1] Total hours worked annually related to fire, police, and/or other public safety operations'' and ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include if any paid EMT/response staff with fire, police, and/or other public safety role was indicated in Section 7, Question 1].''

• Change ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include if any paid Administration/Facilities or medical director staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.2.

• Change ''[Include only if Section 2, Question 7 = ''a'' or ''b.'']'' to ''[Include if any volunteer EMT/response staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.3, Question 2.

• Change ''[Include only if relevant based on responses to Section 7, Question 1 and populate with ''fire,'' ''police,'' and/or ''other public safety'' as appropriate]'' to ''[Include if any volunteer administrative/facilities staff with fire, police, and/or other public safety role were indicated in Section 7, Question 1]'' in Section 7.3, Question 4.

We invite comments on these proposals aiming to better align the printable instrument with the functionality of the programmed instrument and system.

c. Clarifications Responding to Feedback From Interested Parties Questions and Testing

We are proposing 12 instrument changes stemming from feedback we received from emailed questions, during live question and answer and other educational sessions, and via preliminary testing. Specifically, we are proposing to:

• Clarify when and how to report expenses paid for by a local municipality in the Section 1 General Survey Instructions. Several organizations have asked CMS for guidance on how to collect and report data in this scenario. The GADCS FAQ includes several entries related to this question. In brief, whether or not municipal expenses for dispatch services, fuel, facility space, employee benefits, or in any other category must be reported under GADCS depends on the relationship between the ground ambulance organization and the municipality. If the ground ambulance organization is owned and operated by the same municipality paying for the expense, then the expense is in-scope and must be reported. If not, for example in cases where a municipality provides dispatch services to local ground ambulance organizations free of charge, then the expense should not be included. In many cases, ground ambulance organizations can report when a particular input or resource is donated, which likely applies in these cases. To help resolve any ambiguity, we propose to replace the Section 1 text starting with ''If your organization is part of a local government . . .'' with the following text adapted from existing FAQ entries: ''If your organization was part of a municipal government or larger entity that paid for certain ground ambulance expenses (for example, if your municipality pays for rent, benefits, fuel, or dispatch), you must report information on these expenses. This applies only in cases where you are owned or operated by or have a partnership or joint venture with the entity that covers expenses for your ground ambulance operation. In other cases, do not estimate or report the value of donated vehicles, supplies, equipment, or other resources or labor used in your ground ambulance operation. For example, if your local hospital provided drugs at no cost, but you are not a hospital-based ground ambulance organization, then do not report the expense associated with the donated drugs.''

• Remove the text ''in your primary service area (the area in which you usually provide service and where the majority of your transport pickups occur)'' from Section 4 (Emergency Response Time), Question 1, which asks the organization to describe its approach to measuring response times. The intent is for this question to ask about how the organization measures response times across all responses, not just those in their primary service area. Some interested parties shared that they expected to see a corresponding question for their secondary service area. We think this clarification should resolve any ambiguity.

• Add programming notes to the printable instrument noting that a response to Section 4 (Emergency Response Time) questions related to their primary and secondary service areas should be answered only when the organization provided emergency responses in such areas. For example, an organization with both primary and secondary service areas that provided emergency responses in their primary service area but not in their secondary service area should report response time information for their primary but not secondary area. Several organizations have asked how to report information in Section 4 in this case.

• Clarify that the scope of GADCS is limited to ground ambulance operations. For the many ground ambulance organizations that are fire department-based, a Medicare provider, or provide other services beyond ground ambulance services, only a portion of total expenses and revenue are associated with ground ambulance operations. As a result, with the exception of two specific questions (Section 12, Question 1, and Section 13, Question 1), information on expenses and revenue must be reported to GADCS in such a way that CMS can identify an amount associated with or allocated to ground ambulance operations.

• Add guidance throughout Sections 7 through 13 related to allocating a share of expenses and revenue attributable to ground ambulance operations versus other operations (for example, fire, police, or hospital operations). Several ground ambulance

organizations and other interested parties have posed questions to CMS asking for clarification on the specific methods they should use to allocate certain amounts prior to reporting information to GADCS. Allocating expenses is crucial for ground ambulance organizations that also provide other services or functions. If amounts are not allocated appropriately, the expenses and revenue reported to GADCS may be higher or lower than the actual expenses and revenue related to organizations' ground ambulance operations. The current instrument instructions allow ground ambulance organizations to use their current allocation approach or any reasonable alternative. The additional guidance in the instrument would provide an example allocation approach relevant to each section. For example, in fire department-based organizations, respondents can allocate dispatch, fire truck, and firefighter/EMT labor expenses using the share of total responses that are medical calls for service and/or involve a fully staffed and equipped ambulance. As another example relevant to fire department-based organizations, Medicare providers, and some other organizations, respondents can allocate facility expenses based on the share of square footage used by ground ambulance operations. While organizations looking for guidance on an approach could adopt these allocation methods, all organizations would remain free to use alternative allocation methods.

• Add a new screening question asking whether the ground ambulance organization broadly contracts out their ground ambulance organization. We have heard that in some cases a Medicare provider or supplier billing for ground ambulance services and selected to participate in GADCS will pay another organization to provide the entirety of the selected organization's emergency medical services capability, including ambulances, facilities, and EMT/response staff. In other cases, a selected organization may provide ambulances and facilities while some or all EMT/response labor is contracted out to another company. The current instrument instructions ask respondents to report the expenses associated with these broad contracts in Section 11, Question 1. However, the instrument instructions in Sections 7 through 11 do not specify whether the sampled organization should report on staff, facilities, and vehicles that are not owned or leased by the organization itself but instead are provided by the organization with which the sample organization contracts to provide ground ambulance services. If selected organizations that broadly contract out staffing or ground ambulance capabilities report the total contract expenses in Section 11 but do not report on the staff, facilities, and vehicles that their contractor used to provide services in Sections 7 through 9, then the selected organization's expenses will appear very high relative to the inputs they report as necessary to run their ground ambulance operation.

• Add a new screening question in Section 2 that will ask whether organizations contract out some or all of their labor, facilities, vehicles, or other key inputs used to furnish ground ambulance services. We propose that organizations answering ''yes'' to this initial screening question will see new instructions in Sections 7 through 13 asking them to report only select information on inputs provided by their contractors, including staff hours in Section 7, the number of facilities in Section 8, and counts of vehicles in Section 9. Importantly, the additional instruction will stress that organizations should not report on expenses for these contracted inputs in these sections. Organizations should continue to report the total expense for the broadly contracted service in Section 11, Question 1, following the existing instrument instructions. We believe this change will allow those analyzing data collected via GADCS to better align expenses for organizations that broadly contract out their ground ambulance services with the inputs reported via GADCS.

• Clarify (in Chapter 7 (Labor Costs)) for interested parties how to report labor hours and costs for staff categories not explicitly listed in the instrument. The Section 7 instructions already include a note that respondents should include Advanced-EMTs in the EMT-Intermediate category. To more prominently note how to collect and report data on Advanced-EMTs, and to provide more general guidance for other EMT/response labor categories that are State or locality-specific, we propose to add the following instruction in Section 7: ''If your State uses levels of certification and licensure that differ from these categories, use your best judgement to assign staff to the CMS categories available.''

• Revise Section 7 labor category definitions from ''. . . with Fire/Police/Public Safety role'' to read ''. . . with role supporting fire, police, and/or other public safety operations.'' The Section 7 instructions require that staff with fire, police, or other public safety roles be included in separate ''with Fire/Police/Public Safety roles'' categories, regardless of whether they respond to calls for service (for example, as firefighter/EMTs); have a fire, police, or other public safety administrative or management role; or a combination of response and administrative roles. We learned that some ground ambulance organizations interpreted ''with Fire/Police/Public Safety roles'' in Section 7 labor categories to refer only to public safety responses role (that is, responding to calls for service) and not to other fire, police, or other public safety roles (for example, administrative or management roles). We believe this should clarify that our intent is not to limit the question to just fire, police, and other public safety response roles.

The remaining proposed changes in this category relate to clarifying skip logic and response categories. Specifically, we are proposing to:

• Remove the shared service programming note from that question so that all organizations are able to provide a response. When speaking to ambulance organizations, we noted that some organizations that do not meet our definition of shared services (that is, share services with public safety, hospital, or other medical organization) may nonetheless have shared costs with other types of operations. For example, a government-based ground ambulance organization may have computers and printers which are shared by other municipal services. The shared service skip logic programming note was inadvertently included Section 9.2, Question 4. Even without the skip logic, respondents will still be able to report that 100 percent of expenses are related to their ground ambulance operation.

• Streamline the categories and examples presented in the Section 11, Question 3 question on ground ambulance expenses not otherwise reported. We received many questions on how to report certain specific expenses in the provided categories and whether it was appropriate to include a specific expense the ''Other'' category. Specifically, we are proposing to:

++ Change the note in this question that reads ''(excluding labor for medical director if accounted for in Question 1 above or in the labor section)'' to read ''(excluding labor for medical director which must be included in Section 11 Question 1 or in the labor section)'' because expenses associated with Medical Directors may be reported either in Section 7 (Labor Costs) or in Section 11, Question 1.

++ Delete the cost category ''Overhead allocation from parent organization/central office'' as we already provide

places to report these costs throughout relevant sections of the instrument.

++ Move the ''Miscellaneous administrative fees/costs . . .'' category to the end of the ''Administrative and General Expenses'' section to improve flow.

++ Clarify that fees for ''Licenses'' should ''(Include professional or any other license fees not reported elsewhere in the instrument. Do not include any vehicle license fees previously reported in the Vehicles Section.)''

We invite comments on these proposals focusing on improving instrument clarity and consistency in response to feedback from interested parties.

d. Typos and Technical Corrections

The final category of our proposed changes to the instrument address technical corrections and typos. We propose 10 corrections to the data collection instrument. Specifically, we propose to:

- Clarify that Section 4, Question 3 refers to twice the average as intended and as respondents will infer given the flow of questions. The Section 4, Question 3, item refers to the ''90th percentile'' rather than ''twice the average.'' When we removed the question referring to the 90th percentile response time and replaced it with a question asking about the share of responses longer than twice the average response time, as finalized in the CY 2022 PFS final rule (86 FR 65310), we should have but did not also adjust the text in this question.
- Update the Section 7.2 definition to read ''total hours worked by paid administrative/facilities and medical director staff.'' The Section 7.2 instructions define total hours worked as ''total hours worked by paid administrative staff.'' While medical directors are also included in Section 7.2, the current definition inadvertently excludes medical directors.
- Address in the same instrument section, an inadvertent omission in Question 3. This question refers to ''administrative labor costs'' which excludes facility labor costs as is specified throughout the remainder of the section. We would correct this inadvertent omission by replacing ''administrative labor costs'' with ''administrative/facilities costs.''
- Implement a technical correction in Section 8.1, Question 3 which states ''for each of the following types of facilities'' when it should read ''for each of the following facilities.'' The question asks for information at the facility level (not by type of facilities).
- Insert ''rent,'' which was inadvertently omitted, into the Section 8.2, Question 3 text so that it reads ''Please report the allocated portion of rent, lease, or ownership facilities costs. . .''.
- Remove the skip logic and programming note in Section 9.2, Question 4 which erroneously specifies that the total number of statute miles traveled by non-ambulance water vehicles only be asked of organizations that noted in Section 2 that they operated water ambulances. Because organizations may have water rescue vehicles, but no water ambulances, we believe this correction is warranted.
- Remove an extraneous ''ground ambulance'' term in the middle of Section 9.3, Question 4. As a result, the question would read ''What was the total maintenance cost of all vehicles (ground ambulance and non-ambulance) used to respond to ground ambulance calls or support ground ambulance operations ground ambulances during your organization's data collection period?''
- Revise the Section 11 instructions asking for information on allocated central office expenses. The revised question would read ''(Questions 2 and 5)'' instead of just ''(Question 2)'' to align with prior changes in the CY 2022 PFS final rule (86 FR 65313) to ensure respondents can report allocated central office costs throughout the instrument.
- Edit a comma splice in the first sentence of the Section 11 instructions so they begin ''This section asks about . . .''
- Remove the word ''approximate'' as it was erroneously included in Section 13, Question 2b and does not align with any of the other questions in this section.

We invite comments on these proposals to address typos and technical clarifications.

4. Proposed Automation Process for Submitting a Hardship Exemption Request and Informal Review Request

In the CY 2020 PFS final rule (84 FR 62895), we codified the hardship exemption requirement at § 414.626(d). We stated that a ground ambulance organization can apply for a hardship exemption request based on a significant hardship, such as a natural disaster, bankruptcy, or other similar situation, that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

Specifically, § 414.626(d)(1) states that to request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following: Ground ambulance organization name; NPI number; Ground ambulance organization address; Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable); Reason for requesting a hardship exemption; Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.); Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section; and Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization. Section 414.626 (d)(2) states that CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

In the CY 2020 PFS final rule (84 FR 62896), we also codified the process to request an informal review process under which a sampled ground ambulance organization may seek an informal review of a determination that is subject to the 10 percent reduction in payment at § 414.626(e). Section 414.626(e) outlines the notification of non-compliance and informal review. First, for notification of non-compliance, a ground ambulance organization selected under § 414.626 (c) for a year that does not sufficiently report data under paragraph (b) of this section will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9). Second, with respect to informal review, a ground ambulance organization that receives a written notification under § 414.610 (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notification by submitting all of the following information: ground ambulance organization name; NPI number; chief executive officer and any other designated personnel contact

information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization; ground ambulance organization's selected data collection period and data reporting period; and a statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

In the CY 2020 PFS final rule (84 FR 62897), we stated that the hardship exemption and informal review requests should be submitted to the Ambulance ODF mailbox (*AMBULANCEODF@cms.hhs.gov*). We have been looking for ways to streamline both the hardship exemption request and informal review request and have determined that the most efficient method would be to require that the ground ambulance organizations submit a web-based form via the Medicare Ground Ambulance Data Collection System instead of submitting the requests via our Ambulance ODF mailbox. This method would be simpler, less burdensome, and less prone to error to track and process all incoming hardship exemption requests and informal review requests. We intend to launch the web-based portal that ground ambulance organizations can use to submit their hardship exemption and informal review requests in late 2022. We will share more information about the web-based portal when available.

We are also proposing in this proposed rule to update our regulations to give us the necessary flexibility to specify how ground ambulance organizations should submit these requests, including to our web-based portal once that portal is operational. Specifically, we are proposing to revise § 414.626(d)(1) and (e)(2) to state that these requests must be submitted in the form and manner specified by CMS.

As we stated in the CY 2020 PFS final rule (84 FR 62895) and in § 414.626(d)(1), the hardship exemption request form may be accessed on the Ambulances Services Center website for reference.

We invite comments on this proposal.

N. Proposal To Revise HCPCS Level II Coding Procedures for Wound Care Management Products

1. Background

a. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures

Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under that part. In order to process claims and determine payment for items and services under Medicare, CMS needs a way to appropriately identify the items and services billed. CMS has established certain codes for providers and suppliers to use to identify items and services on claims. Medicare receives over 1 billion electronic claims per year.

The HCPCS is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The HCPCS Level I code set is comprised of Current Procedural Terminology (CPT®) codes [346] and the HCPCS Level II code set is used primarily to identify items, services, supplies, and equipment that are not identified by CPT® codes.

HCPCS Level II codes were originally created for use by government insurers including Medicare. On August 17, 2000, HHS published a final rule (65 FR 50312) in which it adopted HCPCS Level II codes as the standard code set to be used by all payers for, among other things, health care equipment and supplies not described by CPT® codes, for use in Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions (45 CFR 162.1002). The HCPCS Level II coding system was selected as the standard code set, in part, because of its wide acceptance among both public and private insurers. With few exceptions,[347] HCPCS Level II codes are maintained by CMS, which is responsible for making decisions about additions, revisions, and discontinuations of the codes. CMS maintains the code set for Medicare but, because HCPCS Level II is a standard code set designated for use under HIPAA by all payers, CMS also considers the needs of other payers, including both government and private insurers, in establishing and maintaining codes.

HCPCS Level II codes are alpha-numeric codes that begin with an alphabetical letter followed by four numeric digits. Currently, there are almost 8,000 HCPCS Level II codes that represent categories of like items and services. Each code includes a text descriptor (code text) that identifies the category of items and services encompassed in the code. HCPCS Level II codes are generally organized into lettered categories that loosely describe the types of codes under that letter; [348] however, the lettered categories are not dispositive, meaning that they are not all inclusive of the types of items and services described in the heading for each lettered category.

Anyone may submit a request to CMS for modifying the HCPCS Level II code set. Three types of coding revisions to the HCPCS may be requested: (1) that a new code be added (this may include requests to split an existing code category into its components or into subcategories); (2) that the language used to describe an existing code be changed; and (3) that an existing code be discontinued. Applicants that choose to submit a HCPCS Level II code application must submit their application using the online application portal known as the Medicare Electronic Application Request Information System™ (MEARIS™).[349]

The procedures by which the public submits and CMS evaluates code applications to modify the HCPCS Level II code set have been primarily included in guidance documents released on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* We update and release the HCPCS Level II dataset files to our contractors and the public via our website on a quarterly basis.

[346] The CPT® is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Decisions regarding the addition, deletion, or revisions of the CPT® codes are made and published by the American Medical Association (AMA) through the CPT® Editorial Panel. More information on CPT® codes can be found at *www.ama-assn/about/cpt-editorial-panel/cpt-code-process.*

[347] The Code on Dental Procedures and Nomenclature (CDT® code) represents a separate medical code set adopted under HIPAA. See 45 CFR 162.1002. Based on alpha-numeric format, they are considered HCPCS Level II series D-codes but are maintained, copyrighted, licensed and published separately by the American Dental Association. More information on CDT® codes can be found at *https://www.ada.org/en/publications/cdt.*

[348] A-codes: Transportation Services, Medical and Surgical Supplies, Miscellaneous; B-codes: Enteral and Parenteral Therapy; C-codes: Hospital Outpatient Prospective Payment System; D-codes: Dental Procedures; E-codes: Durable Medical Equipment; G-codes: Temporary Codes for Procedures and Professional Services; H-codes: Rehabilitative Services; J-codes: Drugs Administered Other Than Oral Method, Chemotherapy Drugs; K-codes: Medicare National Codes for DMEPOS; L-codes: Orthotics, and Prosthetics; M-codes: Medical Services; P-codes: Pathology and Laboratory Services; Q-codes: Medicare National Codes; R-codes: Diagnostic Radiology Services; S-codes: Non-Medicare National Codes; T-codes: State Medicaid Agency Codes; U-codes: Clinical Laboratory Tests; and V-codes: Vision and Hearing Services. 85 FR 70374.

[349] OMB control number 0938–1042. Expiration Date: 07/31/2023.

Prior to 2020, CMS received and reviewed HCPCS Level II code applications and typically made related coding changes annually, including releasing updated coding files. However, in November 2019, we announced updates to our HCPCS Level II coding procedures to enable shorter and more frequent HCPCS Level II code application cycles beginning in January 2020, as part of our initiative to facilitate launching new products into the marketplace for providers and patients. Specifically, we implemented a process under which HCPCS Level II code applications for drugs and biological products may be submitted and are reviewed quarterly and HCPCS Level II code applications for non-drugs and non-biological products may be submitted and are reviewed biannually.

The current coding procedures provide an opportunity for applicants who are dissatisfied with our coding decisions in a quarterly or biannual cycle an opportunity to reapply in a subsequent quarterly or biannual cycle. We release decisions on coding actions on both a quarterly and biannual basis for the respective coding cycle in the same format we used prior to 2020 to announce annual decisions. Additional information pertaining to CMS' HCPCS Level II coding decisions and procedures is available on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.*

b. Food and Drug Administration (FDA) Regulation of Wound Care Management Products

The FDA regulates wound care management products based on a variety of factors, including intended use. Certain wound care management products are considered Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) that are regulated by the FDA solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271 (''361 HCT/Ps''). To be regulated as a 361 HCT/P, the product must meet the four criteria set forth in 21 CFR 1271.10(a):

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- Either, the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function or the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and: (1) Is for autologous use; (2) Is for allogeneic use in a first-degree or second-degree blood relative; or (3) Is for reproductive use.

For 361 HCT/Ps, establishments that perform one or more steps in the manufacture of the HCT/Ps must register and list their HCT/Ps annually in FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval are not needed. FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable FDA rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). Consistent with our proposal in section II.J. of this proposed rule to replace the term ''skin substitutes'' with ''wound care management products,'' we will use the term ''wound care management products'' in our description of the products and related to our proposals below.

Other wound care management products that are regulated by the FDA as devices may be subject to premarket review through a 510(k) premarket notification submission in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations in subpart E of 21 CFR part 807, through the premarket approval (PMA) application process under section 515 of the FD&C Act and regulations in 21 CFR part 814, through a De Novo classification request (De Novo request) under the section 513(f)(2) of the FD&C Act, or are exempt from premarket notification requirements. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as substantially equivalent to a legally marketed device that is not subject to PMA (section 510(k), 510(n), 513(f)(1), or 513(i) of the FD&C Act).[350] A PMA is the most stringent type of premarket device submission and is required for approval of Class III medical devices.[351] The De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. Devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification [510(k)] submissions, when applicable.[352]

2. Proposal To Revise the Requirements Necessary To Obtain a HCPCS Level II Code for Wound Care Management Products

As of May 2022, there are approximately 150 unique HCPCS Level II codes that describe wound care management products. Prior to 2021, all of these products, including those regulated by the FDA as devices, were assigned a Q code as they were generally considered to be biological products and in the office-setting, these products were paid using the methodology under section 1847A of the Act, which, in many cases, is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

In addition, as part of the HCPCS Level II application, CMS required proof of how the product was regulated by the FDA to assist in verification that the product was medical and legally on the market. For example, we required the 510(k) clearance letter or the PMA approval letter for wound care management products that were regulated by the FDA as devices.[353] For 361 HCT/Ps, we required proof that the manufacturer registered and listed their HCT/P with the FDA pursuant to 21 CFR part 1271, for products regulated as 361 HCT/Ps.

Beginning in 2020, in accordance with section 1833(e) of the Act, CMS concluded that each application requesting a HCPCS Level II code for a wound care management product described in the application as a 361 HCT/P include a letter from the FDA's Tissue Reference Group (TRG) recommending that the product appears

[350] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#:~:text=A%20510(k)%20requires%20demonstration,and%20effective%20as%20the%20predicate.&text=the%20information%20submitted%20to%20FDA,as%20the%20legally%20marketed%20device.*

[351] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.*

[352] *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request.*

[353] To date, CMS has not received a HCPCS Level II application for any wound care management product regulated by the FDA as a device through a De Novo request, but a De Novo request approval letter would have been required as part of the application to assist in verification that the product was medical and legally on the market.

to meet the criteria for regulation solely under section 361 of the PHS Act and the regulation in 21 CFR part 1271. This information is necessary for CMS to determine, for coding purposes, how the product should be classified. For example, such information may be necessary to determine whether the product should be coded as a different type of single source biological product rather than as a 361 HCT/P wound care management product.[354] The collection of this additional information was intended to assist us in appropriately classifying for purposes of assigning a HCPCS Level II code when these medical products are 361 HCT/P wound care management products, biological products, drugs, or other.[355]

In the CY 2022 PFS final rule (86 FR 65121), we also finalized that ten specific 510(k)-cleared wound care management products for which we received a HCPCS Level II code application would be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them. In the latter part of 2021, we published final decisions that assigned an A code to each of these ten 510(k)-cleared wound care management products, with an effective date of January 1, 2022. These final decisions are located on the CMS website at *https://www.cms.gov/files/document/2021-hcpcs-application-summary-supplemental-coding-cycle-updated-04062022.pdf.*

We subsequently discovered that we had inadvertently assigned an A code to one product (bio-ConneKt Wound Matrix) for which a Q code, Q4161, had already been assigned. As such, we updated the Supplemental Coding Cycle decision document in December 2021 to remove the A code assignment for bio-ConneKt Wound Matrix while retaining A code assignments for the other nine 510(k)-cleared wound care management products. Following the Supplemental Coding Cycle, we assigned additional A codes for three 510(k)-cleared wound care products with an effective date of April 1, 2022 for which we received a first-time HCPCS Level II application in the Second Biannual, 2021 HCPCS Coding Cycle.[356]

a. General Coding Proposal for All Wound Care Management Products

In this proposed rule, we are proposing to uniformly classify wound care management products (that are not regulated by FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) consistently in the HCPCS Level II code set based on information presented to CMS as described in additional detail below, effective January 1, 2024. That is, we propose that the assignment of A codes to all wound care management products that are not drugs or biological products would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products to which we previously assigned a Q code. See below for further details, as we propose that certain wound care management products will need to submit additional information to CMS prior to the assignment of an A code. This proposal aligns with our proposal in section II.J. of this proposed rule that all wound care management products would be eligible for coverage under section 1861(s)(2)(A) of the Act as incident to supplies that are commonly furnished in the physician office setting.

As stated in the CY 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and HCPCS Level II Proposed Rule (85 FR 70374), HCPCS Level II codes are generally organized into lettered categories that loosely describe the types of codes under that letter. Q codes are used to identify products separately payable as drugs and biologicals under Medicare Part B; such products are priced using methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. A codes are used to identify transportation services and medical and surgical supplies. We believe that the assignment of an A code to all wound care management products that are not drugs or biological products[357] that would otherwise be eligible for separate payment under section 1847A of the Act would better reflect what the product is for purposes of assigning a code as this approach aligns with the payment proposal in section II.J. of this proposed rule that would establish a consistent pricing methodology by pricing all wound care management products as incident to supplies. We also believe this proposed policy would provide a more consistent and transparent approach to coding for wound care management products.

b. Further Detail on 361 HCT/P Proposals

With respect to 361 HCT/P wound care management products, we propose to no longer evaluate HCPCS Level II coding applications for such products on a quarterly basis beginning January 1, 2024,[358] and to instead evaluate them through our biannual coding cycles for non-drugs and non-biological products. We believe our proposal to assign A codes to all wound care management products that are not drugs or biological products and to review these products in the same biannual coding cycle aligns with the payment proposal in section II.J. of this proposed rule, as CMS uses the biannual cycles to review code applications for non-drugs and non-biological products and section II.J is proposing to price these products as incident to supplies. We note that the biannual coding cycle includes preliminary coding determinations and an opportunity for written and public comment, which may assist manufacturers and CMS in reconciling any discrepancies with information submitted to us or addressing questions about a product that we may raise; we believe this dialogue will be productive for all involved.

Manufacturers of products described as 361 HCT/Ps that have already been assigned a Q code must also provide documentation from the FDA (that is, the TRG recommendation letter) that indicates how the product is or appears to be regulated by the FDA.[359] This

[354] Under a final rule promulgated by the FDA on August 31, 2016, manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, must register and list their HCT/Ps following the procedures in 21 CFR part 207 or 807, as applicable, rather than 21 CFR part 1271. FDA also maintains Frequently Asked Questions on this topic at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/questions-and-answers-regarding-end-compliance-and-enforcement-policy-certain-human-cells-tissues-or.*

[355] When a medical product is improperly grouped or described by CMS in the HCPCS Level II code set relative to our established conventions, payers may unintentionally apply inaccurate coverage and/or payment to the provider or supplier submitting a claim, and in that way, the beneficiary or enrollee may be subject to inaccurate cost-sharing. Each payer establishes its own methodology for coverage and payment but often rely on the HCPCS Level II groupings of similar types of medical products to accelerate the adoption process of new technologies.

[356] *https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2–2021-non-drug-and-non-biological-items-and-services.pdf.*

[357] Drug and biological products would generally be coded as J or Q codes.

[358] Manufacturers of wound care management products that received a 510(k) clearance, PMA approval, or a granted De Novo request are currently reviewed in the non-drugs and non-biologicals biannual coding cycle and will continue in that cycle.

[359] Manufacturers of wound care management products that received a 510(k) clearance, PMA approval, or a granted De Novo request do not need to resubmit documentation. These products will be reclassified to an A code at the same time as the established 361 HCT/P products with Q codes are reclassified to an A code (that is, October 1, 2024).

information would be part of a HCPCS Level II re-application submitted via MEARIS™ and would be part of a public meeting for consideration. We are proposing to allow a 12-month period from the effective date of the CY 2023 final rule (that is, January 1, 2024) to allow for re-application submissions. We believe this proposed deadline for re-application submission would provide sufficient time for applicants to communicate with the FDA in regard to the TRG recommendation letter, as applicable. Manufacturers with an existing Q code for products described as 361 HCT/Ps who would need to re-apply for an A code are encouraged to submit their request for a TRG recommendation to the FDA as soon as feasible to ensure that they receive the recommendation in time to include it with the re-application. After a public meeting and appropriate review by CMS, we propose to discontinue all existing Q codes for wound care management products and to establish new A codes for such products that have submitted the appropriate documentation. We propose to make the effective date of the new A codes to coincide with the discontinuation date of the corresponding Q codes such that there would be no gap between the effective dates of the discontinued codes and the newly established codes. Based on our biannual coding process for non-drugs and non-biological products, we anticipate the new A codes would take effect on October 1, 2024. If a re-application is *not* submitted, CMS proposes to discontinue the Q code in the quarterly update cycle following the proposed deadline for re-application submission (that is, January 1, 2024), which we anticipate would take effect on April 1, 2024.

We are also proposing to collect additional information in support of HCPCS Level II code applications for these products. Under our proposal, all first-time applications for 361 HCT/Ps would need to continue to be supported, as we started in 2020, with documentation from the FDA (that is, the TRG recommendation letter) that indicates how the product is or appears to be regulated by the FDA. That is, for a product that is described by the applicant as a 361 HCT/P, we are proposing that the first-time application or re-application would need to provide a recommendation letter from the FDA's TRG which would aid in our determination of how the product should be classified for coding purposes. The FDA TRG recommendation letter assists us in recognizing whether a product is a wound care management product, separately payable drug or biological product, or otherwise and aids us in issuing an appropriate code consistent with our coding conventions.[360] We note that a recommendation letter from FDA's TRG would be necessary in other circumstances, such as when a product manufacturer seeks a change to a current code descriptor or presents other information to us in which a product's market status or other event has changed and the manufacturer believes a code should be revised.

CMS will notify the public of all future coding decisions for wound care management products through its standard process of posting decisions for each coding cycle on the HCPCS web page on *CMS.gov* (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary*).

[360] Based on prior experience, CMS notes that we may identify discrepancies between the FDA TRG recommendation letter and the application presented to CMS, particularly in regard to indications of use and clinical claims. In cases of discrepancies, we may ask for clarification, encourage the applicant to consult further with the FDA, consult further with the FDA ourselves, and/or engage with the applicant through the public meeting process. In doing so, we are working to ascertain that the product is a wound care management product rather than another product, which may be more appropriately classified elsewhere in the HCPCS Level II code set.

c. Summary

In summary, we are proposing: (1) that the assignment of A codes to all wound care management products (that are not regulated by FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products to which we previously assigned a Q code; (2) to discontinue all existing Q codes for wound care management products; (3) to, prior to the assignment of an A code, require products with an existing Q code that were described by the applicant as a 361 HCT/P to submit a HCPCS Level II re-application within 12 months of the effective date of the final rule (that is, January 1, 2024); (4) to require a recommendation letter from the FDA's TRG to be submitted as part of the HCPCS Level II application for all wound care management products described by the applicant as a 361 HCT/P, regardless if it is a first time application or re-application for a product with an existing Q code; and (5) to evaluate HCPCS Level II coding applications for all 361 HCT/P wound care management products through our biannual coding cycles for non-drugs and non-biological products, rather than on a quarterly basis, beginning January 1, 2024.

We are seeking comments on these proposals. We also seek comment on whether any codes have been unintentionally omitted from the list of wound care management products for which new code applications would need to be submitted or new A-codes would be issued for devices that are 510(k)-cleared, PMA-approved, or classified into class I or class II through a De Novo request (Table 74) and should similarly be subject to this proposal.

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TABLE 74: Wound Care Management Products For Which New A-Codes Will Be Issued for 510(k)-cleared/PMA/De Novo Wound Care Management Products or New Code Applications Would Need to Be Submitted Within 12 Months of the Effective Date of the CY 2023 PFS Final Rule

Code	Long Descriptor	Short Descriptor	Effective Date
Q4101	Apligraf, per square centimeter	Apligraf	1/1/2014
Q4102	Oasis wound matrix, per square centimeter	Oasis wound matrix	1/1/2014
Q4103	Oasis burn matrix, per square centimeter	Oasis burn matrix	1/1/2014
Q4104	Integra bilayer matrix wound dressing (bmwd), per square centimeter	Integra bmwd	1/1/2014
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter	Integra drt or omnigraft	1/1/2017
Q4106	Dermagraft, per square centimeter	Dermagraft	1/1/2014
Q4107	Graftjacket, per square centimeter	Graftjacket	1/1/2014
Q4108	Integra matrix, per square centimeter	Integra matrix	1/1/2014
Q4110	Primatrix, per square centimeter	Primatrix	1/1/2014
Q4111	Gammagraft, per square centimeter	Gammagraft	1/1/2014
Q4112	Cymetra, injectable, 1 cc	Cymetra injectable	1/1/2011
Q4113	Graftjacket xpress, injectable, 1 cc	Graftjacket xpress	1/1/2011
Q4114	Integra flowable wound matrix, injectable, 1 cc	Integra flowable wound matri	1/1/2014
Q4115	Alloskin, per square centimeter	Alloskin	1/1/2014
Q4116	Alloderm, per square centimeter	Alloderm	1/1/2014
Q4117	Hyalomatrix, per square centimeter	Hyalomatrix	1/1/2011
Q4118	Matristem micromatrix, 1 mg	Matristem micromatrix	1/1/2014
Q4121	Theraskin, per square centimeter	Theraskin	1/1/2018
Q4122	Dermacell, dermacell awm or dermacell awm porous, per square centimeter	Dermacell, awm, porous sq cm	10/1/2019
Q4123	Alloskin rt, per square centimeter	Alloskin	1/1/2012
Q4124	Oasis ultra tri-layer wound matrix, per square centimeter	Oasis tri-layer wound matrix	1/1/2014
Q4125	Arthroflex, per square centimeter	Arthroflex	1/1/2012
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter	Memoderm/derma/tranz/integup	1/1/2013
Q4127	Talymed, per square centimeter	Talymed	1/1/2016
Q4128	Flex hd, allopatch hd, or matrix hd, per square centimeter	Flexhd/allopatchhd/matrixhd	1/1/2013
Q4130	Strattice tm, per square centimeter	Strattice tm	1/1/2012
Q4132	Grafix core and grafixpl core, per square centimeter	Grafix core, grafixpl core	1/1/2018
Q4133	Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter	Grafix stravix prime pl sqcm	1/1/2019
Q4134	Hmatrix, per square centimeter	Hmatrix	1/1/2013
Q4135	Mediskin, per square centimeter	Mediskin	1/1/2013
Q4136	Ez-derm, per square centimeter	Ezderm	1/1/2013
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter	Amnioexcel biodexcel 1sq cm	1/1/2019
Q4138	Biodfence dryflex, per square centimeter	Biodfence dryflex, 1cm	1/1/2014
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc	Amnio or biodmatrix, inj 1cc	1/1/2014
Q4140	Biodfence, per square centimeter	Biodfence 1cm	1/1/2014
Q4141	Alloskin ac, per square centimeter	Alloskin ac, 1 cm	1/1/2014
Q4142	Xcm biologic tissue matrix, per square centimeter	Xcm biologic tiss matrix 1cm	1/1/2014
Q4143	Repriza, per square centimeter	Repriza, 1cm	1/1/2014
Q4145	Epifix, injectable, 1 mg	Epifix, inj, 1mg	1/1/2014
Q4146	Tensix, per square centimeter	Tensix, 1cm	1/1/2014
Q4147	Architect, architect px, or architect fx, extracellular matrix, per square centimeter	Architect ecm px fx 1 sq cm	1/1/2015
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter	Neox neox rt or clarix cord	1/1/2018
Q4149	Excellagen, 0.1 cc	Excellagen, 0.1 cc	1/1/2014
Q4150	Allowrap ds or dry, per square centimeter	Allowrap ds or dry 1 sq cm	1/1/2015

Code	Long Descriptor	Short Descriptor	Effective Date
Q4151	Amnioband or guardian, per square centimeter	Amnioband, guardian 1 sq cm	1/1/2015
Q4152	Dermapure, per square centimeter	Dermapure 1 square cm	1/1/2015
Q4153	Dermavest and plurivest, per square centimeter	Dermavest, plurivest sq cm	1/1/2016
Q4154	Biovance, per square centimeter	Biovance 1 square cm	1/1/2015
Q4155	Neoxflo or clarixflo, 1 mg	Neoxflo or clarixflo 1 mg	1/1/2015
Q4156	Neox 100 or clarix 100, per square centimeter	Neox 100 or clarix 100	1/1/2018
Q4157	Revitalon, per square centimeter	Revitalon 1 square cm	1/1/2015
Q4158	Kerecis omega3, per square centimeter	Kerecis omega3, per sq cm	1/1/2018
Q4159	Affinity, per square centimeter	Affinity1 square cm	1/1/2015
Q4160	Nushield, per square centimeter	Nushield 1 square cm	1/1/2015
Q4161	Bio-connekt wound matrix, per square centimeter	Bio-connekt per square cm	1/1/2016
Q4162	Woundex flow, bioskin flow, 0.5 cc	Wndex flw, bioskn flw, 0.5cc	1/1/2018
Q4163	Woundex, bioskin, per square centimeter	Woundex, bioskin, per sq cm	1/1/2018
Q4164	Helicoll, per square centimeter	Helicoll, per square cm	1/1/2016
Q4165	Keramatrix or kerasorb, per square centimeter	Keramatrix, kerasorb sq cm	10/1/2019
Q4166	Cytal, per square centimeter	Cytal, per square centimeter	1/1/2017
Q4167	Truskin, per square centimeter	Truskin, per sq centimeter	1/1/2017
Q4168	Amnioband, 1 mg	Amnioband, 1 mg	1/1/2017
Q4169	Artacent wound, per square centimeter	Artacent wound, per sq cm	1/1/2017
Q4170	Cygnus, per square centimeter	Cygnus, per sq cm	1/1/2017
Q4171	Interfyl, 1 mg	Interfyl, 1 mg	1/1/2017
Q4173	Palingen or palingen xplus, per square centimeter	Palingen or palingen xplus	1/1/2017
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc	Palingen or promatrx	1/1/2017
Q4175	Miroderm, per square centimeter	Miroderm	1/1/2017
Q4176	Neopatch or therion, per square centimeter	Neopatch or therion, 1 sq cm	7/1/2020
Q4177	Flowcramnioflo, 0.1 cc	Flowcramnioflo, 0.1 cc	1/1/2018
Q4178	Floweramniopatch, per square centimeter	Floweramniopatch, per sq cm	1/1/2018
Q4179	Flowerderm, per square centimeter	Flowerderm, per sq cm	1/1/2018
Q4180	Revita, per square centimeter	Revita, per sq cm	1/1/2018
Q4181	Amnio wound, per square centimeter	Amnio wound, per square cm	1/1/2018
Q4182	Transcyte, per square centimeter	Transcyte, per sq centimeter	1/1/2018
Q4183	Surgigraft, per square centimeter	Surgigraft, 1 sq cm	1/1/2019
Q4184	Cellesta or cellesta duo, per square centimeter	Cellesta or duo per sq cm	10/1/2019
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc	Cellesta flowab amnion 0.5cc	1/1/2019
Q4186	Epifix, per square centimeter	Epifix 1 sq cm	1/1/2019
Q4187	Epicord, per square centimeter	Epicord 1 sq cm	1/1/2019
Q4188	Amnioarmor, per square centimeter	Amnioarmor 1 sq cm	1/1/2019
Q4189	Artacent ac, 1 mg	Artacent ac, 1 mg	1/1/2019
Q4190	Artacent ac, per square centimeter	Artacent ac 1 sq cm	1/1/2019
Q4191	Restorigin, per square centimeter	Restorigin 1 sq cm	1/1/2019
Q4192	Restorigin, 1 cc	Restorigin, 1 cc	1/1/2019
Q4193	Coll-e-derm, per square centimeter	Coll-e-derm 1 sq cm	1/1/2019
Q4194	Novachor, per square centimeter	Novachor 1 sq cm	1/12019
Q4195	Puraply, per square centimeter	Puraply 1 sq cm	1/1/2019
Q4196	Puraply am, per square centimeter	Puraply am 1 sq cm	1/1/2019
Q4197	Puraply xt, per square centimeter	Puraply xt 1 sq cm	1/1/2019
Q4198	Genesis amniotic membrane, per square centimeter	Genesis amnio membrane 1sqcm	1/1/2019
Q4200	Skin te, per square centimeter	Skin te 1 sq cm	1/1/2019
Q4201	Matrion, per square centimeter	Matrion 1 sq cm	1/1/2019
Q4202	Keroxx (2.5g/cc), 1cc	Keroxx (2.5g/cc), 1cc	1/1/2019
Q4203	Derma-gide, per square centimeter	Derma-gide, 1 sq cm	1/1/2019
Q4204	Xwrap, per square centimeter	Xwrap 1 sq cm	1/1/2019
Q4205	Membrane graft or membrane wrap, per square centimeter	Membrane graft or wrap sq cm	10/1/2019
Q4206	Fluid flow or fluid gf, 1 cc	Fluid flow or fluid gf 1 cc	10/1/2019
Q4208	Novafix, per square cenitmeter	Novafix per sq cm	10/1/2019
Q4209	Surgraft, per square centimeter	Surgraft per sq cm	10/1/2019

Code	Long Descriptor	Short Descriptor	Effective Date
Q4210	Axolotl graft or axolotl dualgraft, per square centimeter	Axolotl graf dualgraf sq cm	10/1/2019
Q4211	Amnion bio or axobiomembrane, per square centimeter	Amnion bio or axobio sq cm	10/1/2019
Q4212	Allogen, per cc	Allogen, per cc	10/1/2019
Q4213	Ascent, 0.5 mg	Ascent, 0.5 mg	10/1/2019
Q4214	Cellesta cord, per square centimeter	Cellesta cord per sq cm	10/1/2019
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg	Axolotl ambient, cryo 0.1 mg	10/1/2019
Q4216	Artacent cord, per square centimeter	Artacent cord per sq cm	10/1/2019
Q4217	Woundfix, biowound, woundfix plus, biowound plus, woundfix xplus or biowound xplus, per square centimeter	Woundfix biowound plus xplus	10/1/2019
Q4218	Surgicord, per square centimeter	Surgicord per sq cm	10/1/2019
Q4219	Surgigraft-dual, per square centimeter	Surgigraft dual per sq cm	10/1/2019
Q4220	Bellacell hd or surederm, per square centimeter	Bellacell hd, surederm sq cm	10/1/2019
Q4221	Amniowrap2, per square centimeter	Amniowrap2 per sq cm	10/1/2019
Q4222	Progenamatrix, per square centimeter	Progenamatrix, per sq cm	10/1/2019
Q4226	Myown skin, includes harvesting and preparation procedures, per square centimeter	Myown harv prep proc sq cm	10/1/2019
Q4227	Amniocore, per square centimeter	Amniocore per sq cm	7/1/2020
Q4229	Cogenex amniotic membrane, per square centimeter	Cogenex amnio memb per sq cm	7/1/2020
Q4230	Cogenex flowable amnion, per 0.5 cc	Cogenex flow amnion 0.5 cc	7/1/2020
Q4231	Corplex p, per cc	Corplex p, per cc	7/1/2020
Q4232	Corplex, per square centimeter	Corplex, per sq cm	7/1/2020
Q4233	Surfactor or nudyn, per 0.5 cc	Surfactor /nudyn per 0.5 cc	7/1/2020
Q4234	Xcellerate, per square centimeter	Xcellerate, per sq cm	7/1/2020
Q4235	Amniorepair or altiply, per square centimeter	Amniorepair or altiply sq cm	7/1/2020
Q4237	Cryo-cord, per square centimeter	Cryo-cord, per sq cm	7/1/2020
Q4238	Derm-maxx, per square centimeter	Derm-maxx, per sq cm	7/1/2020
Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter	Amnio-maxx or lite per sq cm	7/1/2020
Q4240	Corecyte, for topical use only, per 0.5 cc	Corecyte topical only 0.5 cc	7/1/2020
Q4241	Polycyte, for topical use only, per 0.5 cc	Polycyte, topical only 0.5cc	7/1/2020
Q4242	Amniocyte plus, per 0.5 cc	Amniocyte plus, per 0.5 cc	7/1/2020
Q4244	Procenta, per 200 mg	Procenta, per 200 mg	7/1/2020
Q4245	Amniotext, per cc	Amniotext, per cc	7/1/2020
Q4246	Coretext or protext, per cc	Coretext or protext, per cc	7/1/2020
Q4247	Amniotext patch, per square centimeter	Amniotext patch, per sq cm	7/1/2020
Q4248	Dermacyte amniotic membrane allograft, per square centimeter	Dermacyte amn mem allo sq cm	7/1/2020
Q4249	Amniply, for topical use only, per square centimeter	Amniply, per sq cm	10/1/2020
Q4250	Amnioamp-mp, per square centimeter	Amnioamp-mp per sq cm	10/1/2020
Q4254	Novafix dl, per square centimeter	Novafix dl per sq cm	10/1/2020
Q4255	Reguard, for topical use only, per square centimeter	Reguard, topical use per sq	10/1/2020

For all 361 HCT/Ps for which CMS has issued a Q code with an effective date on or after October 1, 2021, as shown in Table 75, we propose to discontinue the Q code and issue an A code, effective on the same date as the other products discussed in this proposal (that is, October 1, 2024). We are not proposing to require resubmission of a HCPCS Level II coding application for these HCT/P wound care management products because the applications already included a TRG recommendation letter from the FDA. We propose to take a similar approach for all new 361 HCT/Ps in which Q codes are issued before January 1, 2024.

TABLE 75: HCPCS Level II Q Codes for Wound Care Management Products Effective on or after October 1, 2021

Code	Long Descriptor	Short Descriptor	Effective Date
Q4251	Vim, per square centimeter	Vim, per square centimeter	10/01/2021
Q4252	Vendaje, per square centimeter	Vendaje, per square centimet	10/01/2021
Q4253	Zenith amniotic membrane, per square centimeter	Zenith amniotic membrane psc	10/01/2021
Q4199	Cygnus matrix, per square centimeter	Cygnus matrix, per sq cm	01/01/2022
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter	Hhf10-p per sq cm	04/01/2022
Q4225	Amniobind, per square centimeter	Amniobind, per sq cm	04/01/2022
Q4256	Mlg-complete, per square centimeter	Mlg complete, per sq cm	04/01/2022
Q4257	Relese, per square centimeter	Relese, per sq cm	04/01/2022
Q4258	Enverse, per square centimeter	Enverse, per sq cm	04/01/2022
Q4259	Celera dual layer or celera dual membrane, per square centimeter	Celera per sq cm	07/01/2022
Q4260	Signature apatch, per square centimeter	Signature apatch, per sq cm	07/01/2022
Q4261	Tag, per square centimeter	Tag, per square centimeter	07/01/2022

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We welcome comment on all of these proposals.

IV. Updates to the Quality Payment Program

A. CY 2023 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2023, except as otherwise noted for specific provisions. The CY 2023 performance period/2025 MIPS payment year continues to move the Quality Payment Program forward to focus more on our measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and encourage participation in Advanced Alternative Payment Models (APMs).

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. The weights of those four performance categories are specified in statute. For CY 2023, those weights are as follows: 30 percent for the quality performance category, 30 percent for the cost performance category, 15 percent for the improvement activities performance category, and 25 percent for the Promoting Interoperability performance category. If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) status, they are excluded from the MIPS reporting requirements and payment adjustment. Those that are qualifying APM participants (QPs) for the year are eligible to receive a 5 percent lump sum incentive payment during the corresponding payment year through CY 2024, or a differential payment update under the PFS for payment years beginning in 2026.

We plan to continue developing Quality Payment Program policies that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with MVPs to allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we make long-term improvements, continue evolving MIPS policies, and plan to begin implementing MVPs in 2023, we remain committed to our program goals. We are aligning with broader CMS initiatives, such as the CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy*), to unify strategic efforts to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures. The vision for the CMS National Quality Strategy is to shape a resilient, high-value American health care system to achieve high-quality, safe, equitable, and accessible care for all. This strategy aims to promote the highest quality outcomes and safest care for all individuals. It also focuses on a person-centric approach as individuals journey across the continuum of care and across payer type. The goals of the strategy incorporate lessons learned from the PHE for COVID–19 to inform both short and long-term direction for our health care system as well as support the creation of a more equitable, safe, and outcomes-based health care system for all individuals. The planned implementation of MVPs aligns with many of the objectives and goals the CMS National Quality Strategy will strive to achieve.

Through the proposals we describe below, we intend to continue improving the MIPS program through MVPs, promote the use of connected measures and activities, reward clinicians for providing high value care, and help all clinicians improve care and engage patients. We also intend to gather information from interested parties to help guide efforts to advance health equity throughout CMS quality programs. We previously finalized an MVP development process involving the submission of MVPs by interested parties for our consideration (85 FR 84849 through 84850). We believe the MVP development process should also consider feedback from the general public outside of the notice and comment rulemaking process through which MVPs are adopted. Therefore, we are proposing to modify the MVP development process such that were

CMS to receive a new candidate MVP, evaluate it through the MVP development process and determine it ''ready'' for feedback, CMS would post a draft version of the MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback from interested parties as well as the general public for a 30-day period.

In addition, we previously established a process for soliciting interested party recommendations for potential updates to established MVPs. On an annual basis, beginning in January, interested parties may submit their recommendations for the revision of an established MVP, and that input is accepted on a rolling basis throughout the year. We believe the MVP maintenance process should also consider feedback from the general public outside of the notice and comment rulemaking process through which MVPs are revised. Therefore, we are proposing that after we review the submitted recommendations to revise established MVPs, and identify any feasible and appropriate revisions to established MVPs, we would host an annual public facing webinar, open to interested parties and the general public through which they may offer their feedback on potential revisions to the MVPs.

Moreover, in the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that will be available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year.

We are proposing revisions to these seven MVPs based on the proposed removals of certain activities from the improvement activities inventory and the addition of other relevant existing quality measures for MVP participants to select from. Through this rulemaking cycle, we are proposing five additional new MVPs:

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

The MVP framework aims to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care. We are continuing to explore opportunities to advance health equity in accordance with the CMS Framework for Health Equity 2022–2023,[361] across all CMS programs and policies, including the MVP framework. We are considering how MVPs should evolve to better promote higher value care and APM participation by both primary care and specialist clinicians. We are seeking public comment, through a request for information (see section IV.A.7.b of this proposed rule), on ways to integrate MVPs into APP reporting and how to best facilitate specialty clinician reporting of quality performance measures (in addition to the APP) that reflect the specialty services provided.

b. Subgroup Reporting

To support clinicians in their transition to subgroup reporting, subgroup reporting will be voluntary for the CY 2023, 2024, and 2025 performance periods/2025, 2026, and 2027 MIPS payment years. Multispecialty groups that choose to report through an MVP will be required to participate as subgroups beginning with CY 2026 performance period/2028 MIPS payment year. As discussed in section IV.A.8.e. of this proposed rule, we are proposing the following policies for subgroups:

- *Subgroup description requirement:* To allow flexibility for groups to explore the different ways they could utilize subgroups, we are not proposing any restrictions related to the composition of a subgroup. Instead, we are proposing that a group must submit a description of each subgroup at the time of registration. We believe that the subgroup description would help us understand the underlying rationale for how groups placed clinicians in a subgroup and help us utilize these characteristics to shape subgroup criteria in the future.
- *Limitation of one subgroup per TIN–NPI combination:* A TIN could choose to form more than one subgroup for reporting MVPs. However, due to operational complexity, we are proposing that an individual eligible clinician, as represented by a TIN/NPI combination may register for no more than one subgroup within a group's TIN.
- *Subgroup determination period:* We are proposing that CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the first segment of the applicable MIPS determination period.
- *Subgroup scores for administrative claims measures and cost measures:* We are proposing that subgroups are scored on each selected population health measure based on their affiliated group score, if available and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We are also proposing that subgroups are scored on the cost measures included in the MVP that they select, based on their affiliated group score, if available. If the affiliated group score is not available, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v). We believe that these policies would help address the issues identified with assessing performance of the administrative claims measures at the subgroup level.
- *Scoring for subgroups that register but do not report:* We are proposing that we will not assign a score for subgroups that register but do not submit data for an applicable performance period.

2. Major APM Provisions

(a) APM Entity Reporting

We are proposing to introduce the option for APM Entities to report the Promoting Interoperability performance category at that APM Entity level.

(b) APM Entity Level Reporting of Promoting Interoperability Performance Category

We are proposing to introduce a voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the 2023 performance period.

(c) Request for Information Regarding QP Determination Calculations at the Individual Eligible Clinician Level

We are including a comment solicitation regarding sunsetting the use of APM Entity level QP determinations and instead making QP determinations at the individual eligible clinician level only.

(d) Payment Based on Quality Measures

We propose revisions to the regulations to clarify that the criterion for Advanced APMs that payment must be based on quality measures can be met through the use of a single quality measure that meets the criteria specified at § 414.1415(b)(2) and (b)(3). We are also proposing conforming changes in the Other Payer Advanced APM regulations.

(e) Generally Applicable Nominal Amount Standard

We are proposing to permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the average

[361] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032., Available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the applicable QP Performance Period, beginning with the 2023 QP Performance Period. We are also proposing conforming changes in the Other Payer Advanced APM regulations.

(f) Medical Home Model 50 Eligible Clinician Limit

We propose to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity. We would identify the eligible clinicians in the APM Entity on each of the three QP determination dates (March 31, June 30, and August 31). This policy would become effective in Performance Year 2023. We are also proposing conforming changes in the Other Payer Advanced APM regulations which will require that the eligible clinician pursuing the option provide the relevant information.

(g) Request for Information Regarding the Transition From APM Incentive Payments to the Enhanced PFS Conversion Factor Update for QPs

We are including a comment solicitation regarding the gap in statutory financial incentives for QPs in the 2025 payment year, and the difference in potential financial incentives between QPs and MIPS eligible clinicians in payment years beginning in 2026.

3. Other MIPS and APM Policies

(a) Quality Performance Category

In section IV.A.10.c.(1)(b) of this proposed rule, we are proposing the following: expand the definition of the term high priority measure to include health equity quality measures; change the CAHPS for MIPS case-mix adjustor for ''Asian language survey completion'' to use instead the ''language other than English spoken at home'' variable; increase the data completeness criteria threshold from 70 percent to 75 percent for the CY 2024 and 2025 performance periods/2026 and 2027 MIPS payment years; and establish a set of 195 quality measures. In section IV.A.10.c.(1)(d) of this proposed rule, we are seeking public comment regarding each of the following topics: the addition of questions related to health disparities and price transparency to the CAHPS for MIPS Survey; the development and implementation of health equity quality measures; and the development and implementation of quality measures that address amputation avoidance in diabetic patients.

(b) Cost Performance Category

In section IV.A.3.b. of this proposed rule, we are proposing to update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group.

(c) Improvement Activities Performance Category

We are proposing to add four new, modify five existing, and remove five existing improvement activities from the Inventory. The new and modified activities help fill gaps we have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. All four of the new activities being proposed relate to CMS Six Health Equity Priorities for Reducing Disparities in Health. We are also recommending the removal of five activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the Inventory offers flexibility and choice without a potentially burdensome number of activities available.

(d) Promoting Interoperability Performance Category

We are proposing several changes to the Promoting Interoperability performance category. Specifically, we are proposing: (1) to require and modify the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points; (2) to expand the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III, and IV drugs; (3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective; (4) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective; (5) to modify the scoring methodology for the Promoting Interoperability performance category; and (6) to continue to reweight the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians.

(e) Payment Adjustment

We are proposing to use the CY 2019 MIPS payment year as the prior period and the rounded mean final score of 75 points from that prior period as the performance threshold for the CY 2025 MIPS payment year.

(f) Scoring

For scoring of the quality performance category, we are proposing to score administrative claims measures using benchmarks calculate from data collected during the performance period and clarifying the topped-out measure lifecycle in instances where a measure is suppressed or otherwise has a benchmark removed. We also include a request for information on which additional risk indicators and data sources we should consider for the complex patient bonus to better assess the social and medical complexity for the patients of MIPS eligible clinicians. Lastly, we are proposing to establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year.

(g) Third Party Intermediaries

We are proposing to update the definition of third party intermediary consistent with existing policies and to make other minor technical edits to the regulation text governing third party intermediaries accordingly. We are also proposing to revise QCDR measure self-nomination and measure approval requirements, including proposing to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year. We are proposing to continue delaying this requirement based on our recognition of the continuing impact of the COVID–19 public health emergency on the ability of QCDRs to test measures. We are also proposing to revise remedial action and termination policies. Finally, we have included two requests for information on third party intermediary support of MVPs and national Continuing Medical Education (CME) organizations becoming a new type of third-party intermediary.

(h) Public Reporting/Physician Compare

In an effort to expand the information available to patients and caregivers when choosing a doctor or clinician, we propose publicly reporting on individual clinician and group profile pages:

- A telehealth indicator, as applicable, and technically feasible, for those clinicians furnishing covered telehealth services.

• Utilization data related to applicable conditions treated and procedures performed by each clinician or group respectively.

Additionally, we would like interested party feedback, through a request for information, on ways to incorporate health equity into public reporting on Care Compare.

c. Continuing To Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs—Request for Information

In the CY 2022 PFS final rule, we stated our aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs (86 FR 65377 through 65382). As part of this modernization of our quality measurement enterprise, we are issuing this request for information to gather additional public input on the transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future notice-and-comment rulemaking. This request for information contains five parts:

• *Background.* This part provides an overview of our goals and strategies to achieve digital quality measurement, and notes input and learnings relevant to these goals and strategies.

• *Potential Refined definition of Digital Quality Measures (dQMs).* This part outlines potential revisions for a future definition for dQMs.

• *Data Standardization Activities to Leverage and Advance Standards for Digital Data.* This part discusses data standardization strategies and potential venues for advancing data standardization.

• *Approaches to Achieve FHIR® eCQM Reporting.* This part describes activities we are undertaking and considering to achieve FHIR-based electronic clinical quality measure (eCQM) reporting (for example, via FHIR Application Programming Interfaces or APIs) as our initial implementation of dQMs.

• *Solicitation of Comments.* This part lists all requests for input included in the sections of this request for information.

(1) Background

In the CY 2022 PFS final rule, we noted the continued focus on use of digital data and advancements in technology and technical standards to improve interoperability of healthcare data which creates opportunity to significantly improve our quality measurement systems (86 FR 65377 through 65382). In a learning health system, standardized and interoperable digital data from a single point of collection can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe data used for quality measurement, as well as these other use cases, should be a seamless outgrowth of data generation from routine workflows. Data sharing should be standards-based to maximize interoperability, minimize burden, and facilitate the development and use of common tooling across use cases. This approach supports data analysis, rapid-cycle feedback, and quality measurement that are aligned for continuous improvement in patient-centered care.

We are continuing to define how we can leverage existing policy to transform all CMS quality measurement to digital reporting, such as policy finalized in the Office of the National Coordinator for Health Information Technology's (ONC) 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, hereinafter referred to as the ONC 21st Century Cures Act final rule (85 FR 25642). In that rule, ONC finalized a ''Standardized API for patient and population services'' certification criterion (45 CFR 170.315(g)(10)) for certified health information technology (IT) requiring the use of FHIR Release 4.0.1 and several other implementation specifications, for health IT modules certified to that criterion. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742). The ONC 21st Century Cures Act final rule (85 FR 25670) also required health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard, Version 1 for all certification criteria that reference it.[362] By aligning technology requirements for payers, healthcare providers, and health IT developers, HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the CY 2022 PFS final rule, we outlined actions in four areas to transition to digital quality measures: (1) leverage and advance standards for digital data and obtain all electronic health record (EHR) data required for quality measures via provider FHIR-based application programming interfaces (APIs); (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate (86 FR 65377 through 65382). The actions are further described in CMS' Digital Quality Measurement Strategic Roadmap available at *https://ecqi.healthit.gov/dQM.* In this request for information, we focus on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to FHIR eCQM reporting in the future, as initial steps in our transition to digital quality measurement.

In the CY 2022 PFS final rule, we also stated our goal of moving to digital quality measurement for all CMS quality reporting and value-based purchasing programs (86 FR 65377 through 65382). We further clarify that we plan to transition incrementally, beginning with the adoption of FHIR API technology and shifting to eCQM reporting using FHIR standards as described in section IV.A.4.d. of this proposed rule. We aim to achieve a quality measurement system fully based on digital measures. The goals of a fully digital measurement system include: reduced burden of reporting; provision of multi-dimensional data in a timely fashion, rapid feedback, and transparent reporting of quality measures; digital measures leveraged for advanced analytics to define, measure, and predict key quality issues; and quality measures that support development of a learning health system, which uses key data that are also used for care, quality improvement, public health, research, etc.

(2) Potential Future Definition of Digital Quality Measures (dQMs)

In the CY 2022 PFS final rule (86 FR 65379), we suggested a potential future definition of dQM for advanced feedback. Based on comments received on the RFI that the term ''software'' is confusing, we are now further revising our potential future definition such that a dQM is a quality measure, organized as self-contained measure specification and code package, that uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. We continue to note potential data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case

[362] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources. We are currently considering how eCQMs, which use EHR data, can be refined or repackaged to fit within the potential future dQM definition. While eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability. In the current state, there are multiple standards that must be supported (for example, Health Quality Measurement Format (HQMF) [363] and Quality Reporting Document Architecture (QRDA) [364]) for eCQM data collection and reporting. Mapping EHR data can be challenging and burdensome for providers as there is often novel data collection occurring to support quality measurement. For example, eCQMs require steps to map data elements from the EHR to the appropriate format. Future dQMs would leverage interoperability standards to decrease mapping burden and align standards for quality measurement with interoperability standards used in other healthcare exchange methods.

We seek comment on this potential future refined definition of dQM and feedback on potential considerations or challenges related to non-EHR data sources.

(3) Data Standardization Activities To Leverage and Advance Standards for Digital Data

As noted in the CY 2022 PFS final rule (86 FR 65379), we are considering implementing eCQM quality reporting via FHIR-based APIs based on standardized, interoperable data. Advancing data standardization is a critical step for this implementation, and for long-term digital measurement strategies. Utilizing standardized data for EHR-based measurement (based on the FHIR standard) and aligning where possible with other interoperability requirements can reduce the data collection burden incurred by providers for the purpose of reporting quality measures. Utilizing standardized data also supports achieving the goals of transitioning to a fully digital quality measurement system identified in section IV.A.4.a. of this proposed rule, including provision of timely feedback, leveraging the same data for multiple use cases, and contributing to a learning health system.

We intend to utilize standardized data for quality measurement as one use case of digital data in a learning health system. In a learning health system, standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe that standardization across data elements and data models is necessary to ensure data are accessible across use cases and enable the transmission of data through each stage of the health system's learning process. Standardized data and FHIR APIs are important for advancing interoperability; the goal is for data to be sent and received via trusted exchanges, and for patients to have access to their data. Operations activities (for example, prior authorization) are also dependent on standardized, interoperable data. Additionally, standardization is necessary across implementation guides, or rules for how a particular interoperability standard should be used,[365] and across value sets that organize the specific terminologies and codes that define clinical concepts.[366]

Commenters on the request for information in the CY 2022 PFS proposed rule encouraged the use of data elements for quality measurement that are consistent with ONC's USCDI standard (45 CFR 170.213),[367] where possible. We agree with this approach. To advance the use of standardized data, models, implementation guides, and value sets in quality measurement, we continue to focus on leveraging the interoperability data requirements for standardized APIs in certified health IT certified to certain certification criteria, set by the ONC 21st Century Cures Act final rule and any future updates made in rulemaking, as a vehicle to support modernization of CMS quality measure reporting. These API requirements are being implemented as part of a series of updates to certified health IT (85 FR 84825), and include availability of data included in the USCDI via standards-based APIs. In the CY 2021 PFS final rule, we finalized that eligible clinicians and eligible hospitals and CAHs participating in MIPS and the Medicare Promoting Interoperability Program, respectively, must transition to use of certified technology updated consistent with the 2015 Edition Cures Update by 2023 (85 FR 84825). We aim to align with these standardized data requirements as the basis for data used in quality measurement.

We are collaborating with Federal agencies to define and prioritize additional data standardization needs and develop consensus with federal partners on recommendations for future versions of the USCDI. We are also directly collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. ONC recently launched the USCDI+ initiative focused on supporting identification and establishment of domain specific datasets that build on the core USCDI foundation.[368] A USCDI+ quality measurement domain currently being explored would support defining additional data specifications for quality measurement that harmonize, where possible, with other Federal agency data needs and inform supplemental standards necessary to support quality measurement.

We also received feedback on the request for information in the CY 2022 PFS proposed rule that the use of Health Level Seven (HL7®) Implementation Guides should be foundational to FHIR measure reporting. To advance implementation of standardized data, we continue to collaborate with consensus standards-setting bodies such as HL7. We are considering how best to leverage existing implementation guides that are routinely updated and maintained by HL7 to define data standards and exchange mechanisms for FHIR-based dQMs, in a fashion that supports the learning health system and alignment across use cases, including the following existing HL7 Implementation Guides:

- U.S. Core Implementation Guide; [369]
- Quality Improvement Core (QI Core) Implementation Guide; [370]
- Data Exchange for Quality Measures (DEQM) Implementation Guide; [371] and
- Quality Measure (QM) Implementation Guide.[372]

[363] *https://www.hl7.org/implement/standards/product_brief.cfm?product_id=97.*

[364] *https://ecqi.healthit.gov/qrda.*

[365] Resource Implementation Guide—Content. Available at *https://www.hl7.org/fhir/implementationguide.html.*

[366] National Library of Medicine, Value Set Authority Center. Available at *https://vsac.nlm.nih.gov/.*

[367] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[368] USCDI+. Available at *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[369] HL7 FHIR US Core Implementation Guide. Available at *http://hl7.org/fhir/us/core/.*

[370] HL7 FHIR QI Core Implementation Guide. Available at *http://hl7.org/fhir/us/qicore/.*

[371] HL7 Data Exchange For Quality Measures. Available at *http://hl7.org/fhir/us/davinci-deqm/.*

[372] HL7 Quality Measure Implementation Guide. Available at *http://hl7.org/fhir/us/cqfmeasures/.*

We are also considering what, if any, additional CMS-specific implementation guides may be necessary to support future digital quality measurement such as guidance on aggregation mechanisms for reporting.

We recognize the importance of considering how implementation guides used across quality measurement and other use cases (for example, public health reporting, clinical decision support) work together to support a learning health system. For example, the Clinical Guidelines (CPG) Implementation Guide [373] connects computable guidelines, clinical decision support, quality reporting, and case reporting. The mechanisms for reporting across use cases are also critical to consider, as each time a different mechanism for reporting is needed across different use cases, it creates more burden. We are collaborating closely with federal partners, such as the Centers for Disease Control and Prevention (CDC), to align where possible.

We believe developing appropriately defined implementation guides will be a key component of supporting standardized FHIR APIs that enable access to standardized data elements for particular use cases, such as quality measurement.

We seek comment on the specific Implementation Guides noted previously, additional Implementation Guides we should consider, and other data and reporting components (for example, data vocabulary/terminology, alignment with other types of reporting) where standardization should be considered to advance data standardization for a learning health system.

(4) Approaches To Achieve FHIR eCQM Reporting

We previously noted in the CY 2022 PFS final rule (86 FR 65379) the activities we are conducting to begin structuring and reporting eCQMs using FHIR. eCQMs are a subset of dQMs. We consider the transition to FHIR-based eCQM reporting the first step to dQM reporting, and a potential model for how future digital reporting can occur.

To support the transition, we continue to undertake and consider activities necessary for reporting of FHIR-based eCQMs and future dQMs:

- In the near term, we plan to continue to convert current Quality Data Model (QDM)-based eCQMs to the FHIR standard and test the implementation of measures re-specified to FHIR and submission of data elements represented in FHIR through ongoing HL7 Connectathons.
- In the near term, we also plan to develop a unified CMS FHIR receiving system. This system would allow for a singular point of data receipt to be used for quality reporting requirements, and modernization of programmatic data receiving systems to leverage opportunities related to digital data.
- We are committed to working with implementers and partners to optimize interoperable data exchange to support FHIR-based eCQM reporting (for example, via FHIR APIs) and eventually other digital quality measures, while ensuring solutions and implementation that require patients to engage with technology also support health equity.
- In the near term, we plan to identify opportunities for the public to provide feedback on FHIR-based measure specifications prior to implementation, such as during measure development/conversion activities.
- We also plan to identify opportunities for collaboration with vendors and implementers via systems testing of FHIR-based eCQM reporting to ensure involvement in systems development.
- Finally, we are exploring venues for continued feedback on CMS future measurement direction and data aggregation approaches in anticipation of FHIR-based API reporting of eCQMs.
- To support both near term FHIR-based eCQMs and other future dQMs, as noted in section IV.A.4.a. of this proposed rule, we intend to continue engaging with standards development organizations to advance and maintain implementation guides to support the FHIR standard and API reporting of quality measures.
- We also anticipate that prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors.

We also continue to consider how best to leverage the ONC interoperability certification criteria related to implementing FHIR API technology to access and electronically transmit interoperable data for quality measurement. Based on feedback on the CY 2022 PFS proposed rule request for information, many supported the use of FHIR APIs, while others expressed concern around infrastructure readiness. We continue to explore how to leverage FHIR APIs to decrease reporting burden and support implementor readiness. We seek comment on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR APIs, and to combine data needed for measure score calculation for measures that require aggregating data across multiple providers (for example, risk-adjusted outcome measures) and multiple data sources (for example, hybrid claims-EHR measures). We are interested in data flows that support using the same data for measurement and to provide feedback to providers at multiple levels of accountability, such as at the individual clinician, group, accountable care organization and health plan levels, as are used for patient care and other use cases (for example, public health reporting).

We seek comment on additional venues to engage with implementors during the transition to digital quality measurement, and other critical considerations during the transition. We also seek comment on data flow options to support FHIR-based eCQM reporting.

(5) Solicitation of Comments

As noted previously, we seek input on the following:

- Refined potential future Definition of dQMs. We are seeking feedback on the following as described in section IV.A.4.b. of this proposed rule:

++ Do you have feedback on the potential refined definition of digital quality measures (dQMs)?

++ Do you have feedback on potential considerations or challenges related to non-EHR data sources?

- Data Standardization Activities to Leverage and Advance Standards for Digital Data. We are seeking feedback on the following as described in section IV.A.4.c. of this proposed rule:

++ Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?

- Approaches to Achieve FHIR eCQM Reporting. We are seeking feedback on the following as described in section IV.A.4.d. of this proposed rule:

++ Are there additional venues to engage with implementors during the transition to digital quality measurement?

++ What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?

[373] HL7 FHIR Clinical Guidelines Implementation Guide. Available at *http://hl7.org/fhir/uv/cpg/.*

++ Are there other critical considerations during the transition?

B. Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)—Request for Information

Section 4003(b) of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted on December 13, 2016), amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purposes of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common Agreement (TEFCA). ONC's goals for TEFCA are as follows:

Goal 1: Establish a universal policy and technical floor for nationwide interoperability.

Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

Goal 3: Enable individuals to gather their health care information.[374]

On January 18, 2022, ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [375] and Common Agreement Version 1.[376] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) [377] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The Common Agreement is a legal contract that QHINs [378] sign with the ONC Recognized Coordinating Entity (RCE),[379] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) [380] Providers.[381] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[382] Compared to most nationwide exchange today, the Common Agreement includes an expanded set of Exchange Purposes beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination [383]—all built upon common technical and policy requirements to meet key needs of the U.S. health care system. This flexible structure allows interested parties to participate in the way that makes most sense for them, while supporting simplified, seamless exchange.

The QTF,[384] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) [385] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable different types of information exchange, including querying and message delivery across participating entities.

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects interested parties across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such interested parties would be: (1) signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [386] under the

[374] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[375] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[376] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[377] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[378] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[379] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage interested parties to create a roadmap for expanding interoperability over time. *See* ONC Awards The Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information (September 3, 2019), *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information.*

[380] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[381] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[382] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[383] For the Common Agreement definitions of Payment, Health Care Operations, Public Health, and Government Benefits Determination, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6–10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[384] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[385] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[386] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the

Common Agreement), (2) in good standing (that is, not suspended) under that agreement, and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient, access to more health information while requiring strong privacy and security protections.

We believe that exchange of health information enabled by the Common Agreement can advance CMS policy and program objectives related to care coordination, cost efficiency, and patient-centeredness in a variety of ways. We also believe that CMS policy and programs can help to accelerate nationwide connectivity through TEFCA by health care providers as well as other interested parties.

As discussed in section IV.A.10.c.(4)(e) of this proposed rule, we are proposing to add a new Enabling Exchange Under TEFCA measure in the Promoting Interoperability performance category. This proposed measure would provide eligible clinicians with the opportunity to earn credit for the Health Information Exchange objective if they: are a signatory to a ''Framework Agreement'' as that term is defined in the Common Agreement; enable secure, bi-directional exchange of information to occur for all unique patients of eligible clinicians, and all unique patient records stored or maintained in the EHR; and use the functions of CEHRT to support bi-directional exchange.

In addition to this proposal, we are considering other ways that available CMS policy and program levers can advance information exchange under TEFCA. For instance, similar to the proposal in the current rule, there may be opportunities for CMS to incentivize exchange under TEFCA through other programs that incentivize high quality care, or through program features in value-based payment models that encourage certain activities that can improve care delivery.

In addition to programs focused on health care providers, we are interested in opportunities to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. For instance, we believe there may be opportunities to encourage information exchange under TEFCA to support recently finalized requirements for these payers to make information available to patients and to make patient information available to other payers as beneficiaries transition between plans in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers'' final rule (85 FR 25510). Finally, we are considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes.

We are requesting input from the public on the ideas described previously and related concepts for future exploration, as well as the following questions:

- What are the most important use cases for different groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?

- What are key ways that the capabilities of TEFCA can help to advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different interested parties, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in order to advance exchange under TEFCA?

- How should CMS approach incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by interested parties for specific use cases?

- What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some interested parties? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

C. Definitions

At § 414.1305, we are proposing revisions to the definitions of the following terms:

- Multispecialty group;
- Single specialty group;
- Facility-based group;
- Facility-based MIPS eligible clinician
- High priority measure; and
- Third party intermediary.

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

7. Transforming MIPS: MVP Strategy

a. MVP Vision Overview

We are moving to MIPS Value Pathways (MVPs) to improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to participation in Alternative Payment Models (APMs). We intend to promote high value care by connecting performance on cost, quality, and patient experience of care to payment. We believe the MVP framework will move MIPS forward on the path to value by connecting the MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability. The MVP framework aims to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care. We intend for MVPs to drive value and help clinicians and practices prepare to take on and manage financial risk, for example, through Advanced APMs, as they build out their quality infrastructure components and gain experience with cost measurement. We envision that MVPs, in which there is aligned measurement of quality of care and cost, continuous improvement and innovation within the practice, and efficient management and transfers of information, will help clinicians deliver higher value care and remove barriers to APM participation. Combining linked performance measures and activities with more standardization and focused reporting of meaningful measures in MVPs will, we believe, produce data that can better assist patients in comparing clinician performance and in selecting clinicians. Such data can also assist clinicians in making care improvements and making appropriate specialist referrals. As more clinicians have applicable MVPs available, the performance data available to patients will expand, and in the future, information on specialists in

Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

multispecialty groups will increase on our Compare Tools, enabling patients to make more informed choices for their care. MVPs will be available for voluntary reporting beginning with the CY 2023 MIPS performance period, and we intend for MVPs to become the only method to participate in MIPS in future years, although we have not yet finalized the timing for the sunset of traditional MIPS.[387]

We are continuing to explore opportunities to advance health equity across all CMS programs and policies. The CMS Office of Minority Health released *Paving the Way to Equity: A Progress Report* in 2021, which describes the CMS Equity Plan for Medicare and progress from 2015 to 2021.[388] The progress report considers emerging opportunities to build on progress with a focus on CMS current strategic initiatives, HHS priorities, and areas in which CMS quality improvement efforts will move forward.[389] MIPS improvement activities that support and recognize impactful disparities reduction efforts are acknowledged in the CMS *Equity Progress Report.*[390] More recently, on April 22, 2022, the CMS Office of Minority Health released the *CMS Framework for Health Equity,*[391] which updates the CMS Equity Plan with an enhanced and more comprehensive 10-year approach to further embed health equity across CMS programs including Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces. This CMS Framework for Health Equity outlines five priorities: (1) Expand the collection, reporting and analysis of standardized data; (2) Assess causes of disparities within CMS programs, and address inequities in policies and operations to close gaps; (3) Build capacity of health care organizations and the workforce to reduce health and health care disparities; (4) Advance language access, health literacy, and the provision of culturally tailored services; and (5) Increase all forms of accessibility to health care services and coverage.[392] We intend to use this health equity framework across CMS to design, implement, and operationalize policies to support health for all people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.

We are considering ways that we can advance health equity via the Quality Payment Program. As we implement MVPs, we are considering how best to further the five priorities of the CMS Framework for Health Equity. We intend for both MVPs and APMs to advance health equity and increase the value of health care for all as we leverage improvement activities, quality measure performance data, and public reporting. We anticipate that MVPs and APMs will have greater impact on health equity as participation grows. The CMS Center for Medicare & Medicaid Innovation's (CMMI) strategy refresh white paper[393] includes advancing health equity as one of five objectives that guide CMMI's models, priorities, and assessment of impact.[394] In this CY 2023 PFS proposed rule we consider approaches for advancing health equity in MIPS in section IV.A.10.c.(1)(b) through IV.A.10.c.(1)(d) of this proposed rule. See section IV.A.10.c.(1)(c)(i) of this proposed rule regarding potential next steps related to a proposed social determinants of health quality measure. See sections IV.A.10.c.(1)(d) and IV.A.10.h.(3) for our request for comment on the inclusion of a health equity measure in MIPS and MIPS Compare Tool public reporting in the future.

We presented our MVP vision and guiding principles in the CY 2021 PFS final rule (85 FR 84844 through 84845). We intend for MVP implementation to drive value, obtain comparative performance data, and elevate the patient voice while reducing clinician burden. We strive to achieve meaningful performance measurement, burden reduction, scoring equity, and increased value. The MVP framework was discussed in the CY 2020 and the CY 2021 PFS proposed rules (84 FR 40732 through 40734, and 85 FR 50279, respectively) and CY 2021 PFS final rule (85 FR 84844 through 84845). Our MVP framework calls for linking the quality, cost, and improvement activities performance categories, as well as a foundation of required reporting for the Promoting Interoperability performance category and population health claims-based quality performance category measures. We continue to consider how to best implement an MVP portfolio that balances our MVP goals for transformative change and our five MVP guiding principles as discussed in the CY 2021 PFS final rule (85 FR 84845 through 84546) within current CMS and clinician practice capabilities. We previously described in the CY 2022 PFS proposed rule (86 FR 39354) how we are beginning to implement the MVP guiding principles, and in the CY 2019 PFS proposed rule (83 FR 40732 through 40733) we discussed how MVPs can help ready clinicians for APM participation. We finalized policies around MVP reporting by subgroups (CY 2022 PFS final rule, 86 FR 654398 through 65401) that allow specialty clinicians to report meaningful performance information to MIPS and that better represents the non-primary care, specialty services provided. We also continue to develop MVP subgroup reporting policies and propose a modification of the definition of single specialty and multispecialty group to include claims as the data source used in the specialty determination (see section IV.A.8.e.(2) of this proposed rule). We continue to contemplate how to support specialty clinician reporting for APM participants who report to MIPS through the APM Performance Pathway (APP) and potentially MVPs. See CY 2021 PFS final rule (85 FR 84860) and section IV.A.9.b. of this proposed rule for details on the APP. We are also considering how MVPs should evolve to better promote higher value care and APM participation by both primary care and specialist clinicians.

b. MVPs and APM Participant Reporting Request for Information

(1) Overview

MVPs and APMs share a goal of meaningful performance measurement and burden reduction, along with objectives of scoring equity and advancing value. Interested parties have requested more options for meaningful specialty clinician participation within both the MVP framework and APMs (85 FR 84845 and 86 FR 65391). We have developed MVP and subgroup reporting policies to provide meaningful MIPS performance measurement for both primary care and specialist clinicians (86 FR 65414). We received requests from interested parties to further define the relationship between MVPs and

[387] 42 CFR 414.1365(a)(1).

[388] CMS, *Paving the Way to Equity: A Progress Report (2015–2021)* (2021) (hereinafter the ''CMS Equity Progress Report''), available at *https://www.cms.gov/sites/default/files/2021-01/Paving%20the%20Way%20to%20Equity%20CMS%20OMH%20Progress%20Report.pdf;* CMS, *CMS Equity Plan for Improving Quality in Medicare* (Sep. 2015), (hereinafter the ''CMS Equity Plan'') available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[389] Ibid., at 2–3.

[390] *CMS Equity Progress Report* at 28.

[391] CMS, *CMS Framework for Health Equity,* available at *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[392] Ibid., at 10–11.

[393] CMS, Innovation Center Strategy White Refresh (Oct. 2021), available at *https://innovation.cms.gov/strategic-direction-whitepaper.*

[394] Ibid., at 18–21.

APMs and previously requested public feedback on this topic (86 FR 39354 and 39355). We sought public feedback via a request for comment in the CY 2022 PFS proposed rule on innovative approaches to achieving our desired MVP goals to improve value, reduce burden, help patients compare clinician performance, and reduce barriers to joining APMs (86 FR 39353 and 39354). We discussed how to best coordinate and align MVPs and APMs and noted we would continue to explore the ideal MVP relationship with APMs to drive value (86 FR 39354). While we did not summarize the responses to this request for comment in the CY 2022 PFS final rule, several commenters requested to see close alignment between MVPs and APMs. Some commenters specifically suggested using APM measures in MVPs and others suggested we adopt a flexible MVP framework similar to APMs in that it centers on quality improvement, efficient resource use, patient reported outcomes and satisfaction, and enhanced technology to care for patients with specific medical conditions. A few commenters referred to challenges for specialists in reporting quality performance data under MIPS and their respective APM separately, resulting in additional reporting burden. We are considering what close alignment between MVPs and APMs would mean and welcome additional feedback as more MVPs are developed. We seek public comments on addressing the challenges commenters noted regarding specialist reporting of quality performance data and outline concepts in this section of this proposed rule.

We recognize a gap in the availability of specialty clinician performance data for APM participants to inform patient selection of clinicians based on clinician quality and value improvement data. Of the 933,547 MIPS eligible clinicians receiving a MIPS payment adjustment for the 2020 performance year, 398,719 participated in MIPS as APM participants, a significant 42.7 percent (*qpp.cms.gov*).[395]

We acknowledge the 2022–2024 APM Performance Pathway (APP) measure set (86 FR 65431) may not fully represent the services provided and the patients treated by all clinician types in a group, for example, when a group includes multiple specialties, such as emergency medicine, orthopedic surgery, and neurology in the Medicare program. We expect many clinicians who are part of APMs and do not attain QP status will report for MIPS using the APP. We seek ideas for how we could obtain more robust reporting of both primary care and specialty care performance measurement information from APM participants. We would like to consider policy ideas that would encourage the reporting of specialty services performance information in addition to the APP, for example and to the extent feasible, by extending APP scoring policies for the cost and improvement activities performance categories outside the APP, finding a way to roll MVP quality measure performance data into the APP, or by some other method. These policy options should be considered in conjunction with the proposals in sections IV.A.8.e.(3) and IV.A.9.b. of this proposed rule where we request input on policies to formalize subgroup registration and reporting of the APP.

As we move forward with MVP implementation, we continue to seek feedback on ways to better align clinician experience between MVPs and APMs, and to ensure that MVP reporting serves as a bridge to APM participation. While we believe that MVPs will serve an important role in furthering specialty measurement, we also believe that primary care measurement will be integral to MIPS. We envision MVP reporting to complement APP reporting such that it will enhance performance measurement and available information while minimizing additional burden. We look for feedback on the benefits and disadvantages of various approaches, keeping in mind our goals of enhancing specialty specific performance measurement and available information for patients while also minimizing complexity where possible.

We continue to solicit input as we consider solutions, the direction of our MVP framework, and its intersection with APMs.

(2) Solicitation of Comments

We are seeking feedback on the following as described in section IV.A.7.b.(1) of this proposed rule:

- How should we use MVPs to obtain more meaningful performance data from both primary care and specialty clinicians and drive improvements for APP reporters and APM participants? What are the associated pros and cons for the suggested solution(s)?
- How should we better align clinician experience with MVPs and APMs, and ensure that MVP reporting serves as a bridge to APM participation?
- How should we best limit burden and develop scoring policies for APM participants in multispecialty groups who choose to participate in MVPs and report specialty care performance data? Should we require APP participants to focus on those clinicians who work in the associated quality measurement clinical area and require subgroup reporting of relevant MVPs for others? Should we develop a process for a composite score that incorporates both APP measures and other MVP specialty measures?
- What other policy options for MIPS specialty clinician performance data reporting should we consider?

8. MVP Development and Reporting Requirements

a. MVP Development

(1) Development of New MVPs

We intend to develop MVPs, to the extent feasible and appropriate, by including interested parties in the process (85 FR 84849 and 84850). For a description of the current process for developing new MVPs, we refer readers to the CY 2021 PFS final rule (85 FR 84849 through 84856). Commenters suggested that we work in tandem with clinicians and specialty societies to develop MVPs (84 FR 62948) and have supported the development of MVPs with robust input from interested parties and feedback opportunities. While this process has provided value in the development of meaningful MVPs for the program, we agree and believe that we should also consider feedback during the MVP development process from a wide range of interested parties and the general public before the notice and comment rulemaking process. By creating the opportunity for feedback earlier in the MVP development process, we hope to receive a broader set of perspectives on a draft MVP, including the perspectives of: patients, patient advocates, practices that serve underserved and rural areas, specialty organizations, health systems, and the general public. We believe it is important to receive feedback from interested parties and the general public early in the MVP development process to ensure the MVPs that are developed are meaningful and resonate with clinicians- including those who serve patients in small practices, or in rural or underserved areas where patient populations may face health equity barriers. Clinicians may use the results of MVP reporting results to determine areas of practice improvement, and identify gaps in clinical outcomes. In addition, patients may leverage the granular data ascertained through MVP reporting to make informed decisions

[395] QUALITY PAYMENT PROGRAM PARTICIPATION IN 2020: RESULTS AT-A-GLANCE, available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1783/QPP%202020%20Participation%20Results%20Infographic.pdf.*

when selecting a clinician or specialist to participate in their care.

Therefore, we propose to modify the MVP development process such that we would evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we would post a draft version of the submitted candidate MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. Interested parties and the general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we would not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. We request comments on this proposal.

(2) MVP Maintenance Process and Engagement With Interested Parties

In the CY 2022 PFS final rule (86 FR 65410), we finalized an annual maintenance process for MVPs that were previously finalized through notice and comment rulemaking. We established a process for soliciting recommendations from interested parties for potential updates to finalized MVPs. As part of this process, beginning in January of the year prior to the performance period, interested parties may submit recommendations to revise an MVP that was previously finalized through rulemaking. Recommendations from interested parties will be accepted on a rolling basis throughout the year. We stated that we would be unable to communicate with interested parties as to whether their recommendations were accepted ahead of rulemaking, and that we would ultimately determine whether updates to the established MVPs should be made (86 FR 65410). We stated that we would consult with the interested parties who originally nominated the MVP about any publicly recommended changes to the MVP (86 FR 65410).

Similar to the proposed updates to the process for developing new MVPs, discussed in section IV.A.8.a.(1) of this proposed rule, and for the same reasons, we believe that we should also consider feedback during the MVP maintenance process, from a wide range of interested parties and the general public, prior to proposing changes to an existing MVP through the notice and comment rulemaking process. Therefore, we propose to modify the MVP maintenance process such that interested parties and the general public would be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. If we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. These proposed changes to the MVP maintenance process would enable us to receive a wide range of perspectives on potential revisions to MVPs earlier in the maintenance process, which we believe is important in developing MVPs that are meaningful to clinicians, patients, and the general public. If we decide to make any revisions to an established MVP based on the recommendations submitted, we would adopt such revisions through notice and comment rulemaking. We request comments on this proposal.

(3) Proposed Revisions to Previously Finalized MVPs

In the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that will be available for reporting beginning with the CY 2023 performance period/CY 2025 MIPS payment year. The seven MVPs are as follows: *Advancing Rheumatology Patient Care; Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes; Advancing Care for Heart Disease; Optimizing Chronic Disease Management; Adopting Best Practices and Promoting Patient Safety within Emergency Medicine; Improving Care for Lower Extremity Joint Repair; and Patient Safety and Support of Positive Experiences with Anesthesia.* We are proposing revisions to these seven MVPs based on the proposed removals of certain activities from the improvement activities inventory and the addition of other relevant existing quality measures for MVP participants to select from. We refer readers to Appendix 3: MVP Inventory of this proposed rule for these proposed revisions and our explanation of why we believe these changes are appropriate.

(4) Proposed New MVPs

Through our established development processes for new MVPs (85 FR 84849 through 84856) we aim to gradually develop MVPs that are relevant and meaningful for all clinicians who participate in MIPs. We are proposing five new MVPs:

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

We continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip.* The identification of priorities includes consideration of the various specialties and subspecialties that currently participate in MIPS, and identification of priorities of the Biden-Harris Administration, Department, and Agency. For example, in support of the Biden-Harris Administration's Cancer Moonshot Mission [396] and the importance of cancer screening and care, we are proposing a new MVP related to cancer care.

We refer readers to Appendix 3: MVP Inventory of this proposed rule where we discuss each proposed new MVP, including which specific measures and activities would be included, and the clinician types for which a proposed new MVP may be relevant.

b. MVP Reporting Requirements

(1) Promoting Interoperability

In the CY 2021 PFS final rule (85 FR 84849 through 84854), we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b). We refer readers to

[396] White House, Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Knot It (Feb. 2. 2022), available at *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it.*

section IV.A.10.c.(4) of this proposed rule for proposed modifications to the Query of Prescription Drug Monitoring Program (PDMP) measure, the Public Health and Clinical Data Exchange Objective, and the Health Information Exchange Objective. In addition, section IV.A.10.c.(4) of this proposed rule includes proposals related to reweighting the Promoting Interoperability performance category for non-physician clinician types, and modifying the Promoting Interoperability scoring methodology beginning with the CY 2023 performance period/CY 2025 MIPS payment year. We intend for any changes that are finalized for the Promoting Interoperability performance category under traditional MIPS to apply to MVPs.

c. Reporting MVPs and Team-Based Care

In the CY 2022 PFS final rule (86 FR 65406), we discussed that MVPs may be constructed to reflect the team-based healthcare model. This approach considers the patient's care from a holistic perspective, involving several clinician types in a manner that captures the patient's experience and outcomes. We have received questions from interested parties asking how a large multispecialty group that practices team-based care can report MVPs, and if subgroup reporting would mean that each individual specialty within the practice would have to report its own MVP. In this proposed rule, we are providing some clarification on a few options of how multispecialty groups who practice in a team-based care manner can report MVPs.

In the CY 2022 PFS final rule (86 FR 65392 through 65394), we finalized that for the CY 2023, 2024, and 2025 performance periods, individual MIPS eligible clinicians, single specialty groups, multispecialty groups, subgroups and APM entities may report MVPs. We also finalized that beginning with the CY 2026 performance period, multispecialty groups must form subgroups to report MVPs (86 FR 65394). We encourage multispecialty groups to review the inventory of available MVPs that we have implemented to identify whether a relevant MVP is available to them. If a multispecialty group identifies an MVP that is relevant to its practice, the group may register through the MVP registration process to report that single MVP (86 FR 65415 through 65418). We encourage a multispecialty group to choose an MVP that includes measures that are attributable to all clinician types that participate in its group, if it intends to report as a multispecialty group within the first few years of its MVP reporting. We believe that reporting data that is directly attributed to all clinicians in the group will better drive quality improvement and lead to improved patient outcomes.

We encourage multispecialty groups to consider adopting subgroup reporting before it becomes mandatory in the CY 2026 performance period. Early adoption will allow clinicians within the subgroups to gain familiarity with reporting at the subgroup level before it becomes mandatory. We refer readers to the CY 2022 PFS final rule (86 FR 65398 through 65405) and section IV.A.8.e. of this proposed rule where we discuss our proposals regarding subgroup policies and subgroup composition. In support of team-based care, we have not proposed any criteria which would limit the number of specialties within a subgroup. A multispecialty group should use its discretion in determining the most operationally feasible and appropriate way to report MVPs via subgroup reporting before mandatory subgroup reporting begins in CY 2026. For example, choosing a few clinically relevant specialties from the group to form a subgroup (that is, orthopedic surgeons, physical therapists, nurse practitioners or physician assistants who are specialized in the area of orthopedics) to report on a single MVP related to orthopedic surgery. While we understand there may be an increase to the burden associated with requiring multispecialty groups to report through subgroups beginning with the CY 2026 performance period, we believe MVP reporting will have more value because the data will be directly attributed to the clinicians leading to actionable changes in the care provided to patients.

d. Scoring MVP Performance

In the CY 2022 PFS final rule, we finalized policies for MVP scoring beginning with the CY 2023 performance period/CY 2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d)(2), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we intend to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419).

We refer readers to section IV.A.10.d.(1)(b)(i) of this proposed rule for our proposal on the determination of benchmarks for administrative claims quality measures, section IV.A.10.d.(1)(b)(ii) for our proposal on assigning measure achievement points for topped out quality measures, section IV.A.10.d.(1)(c)(i) for our proposal regarding improvement scoring for cost measures, and section IV.A.10.c.(4)(g) for our proposals regarding changes to the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2023. In the event these proposals and any other scoring policies for traditional MIPS are adopted as final policy, they would apply to the measures and activities included in the MVP, unless otherwise indicated.

In the CY 2022 PFS final rule, we finalized the subgroup reporting option for clinicians choosing to report MVPs or the APP (86 FR 65392 through 65394). We refer readers to section V.B.9.e.(7)(a)(ii) of this proposed rule for the discussion on estimated burden associated with subgroup reporting. The relevant burden will be submitted to OMB under control number 0938–1314 (CMS–10621). Subgroup reporting is a new option for clinicians, and, for clarity, we discuss all proposals regarding subgroups, including scoring, in a single section of this proposed rule at section IV.A.8.e. We refer readers to section IV.A.8.e.(4)(b) of this proposed rule for our proposals related to subgroup scoring for administrative claims and cost measures and section IV.A.8.e.(4)(c) of this proposed rule for our proposal related to scoring for subgroups that register but do not report.

e. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to report through subgroups beginning with the CY 2023 performance period/CY 2025 MIPS payment year (86 FR 65392 through 65394). Additionally, we finalized: (1) A timeline for implementing subgroup reporting (86 FR 65396 and 65397); (2) registration requirements, reporting requirements, and scoring policies for clinicians desiring to report MVPs through subgroups (§ 414.1365; 86 FR 65415 through 65426); (3) definitions of subgroup, single specialty group, multispecialty group, and special status (§ 414.1305; 86 FR 65398 through 65401); (4) subgroup eligibility requirements (§ 414.1318; 86 FR 65401); (5) application of low-volume threshold and special status designations for

subgroups (§ 414.1318(a)(2); 86 FR 65401 and 65402); and (6) subgroup inclusions and exclusions (§ 414.1318; 86 FR 65402 and 65403).

In this section, we propose to: (1) modify the definitions of single specialty group and multispecialty group; (2) add subgroup description requirements to the registration process; (3) limit the number of subgroups a clinician may participate in to one subgroup per TIN; (4) establish the subgroup determination period; (5) apply new policies for scoring administrative claims measures and cost measures for subgroups; and (6) not assign a subgroup final score to registered subgroups that do not submit data.

(2) Definitions of a Single Specialty Group and a Multispecialty Group

We previously finalized at § 414.1305 the definitions of a single specialty group as a group that consists of one specialty type, and a multispecialty group as a group that consists of two or more specialty types. We also finalized at § 414.1305 the definition of an MVP participant for the purpose of MVP reporting. The definition of MVP Participant established in the CY 2022 PFS final rule (86 FR 65392 through 65394) would only allow multispecialty groups to participate as a group for MVP reporting beginning with the CY 2023 performance period/CY 2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year. Beginning with the CY 2026 performance period/CY 2028 MIPS payment year, only single specialty groups would be able to participate as a group for MVP reporting, and multispecialty groups will be required to form subgroups for reporting an MVP. We believe that the definitions of single specialty group and multispecialty group would allow groups to distinguish their specialty type or types and assess the requirement to participate as a subgroup in MVP reporting beginning with the CY 2026 performance period/CY 2028 MIPS payment year. In the CY 2022 PFS proposed rule (86 FR 39360), we proposed to identify a group's specialty type or types using data from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We received comments expressing concerns that the use of PECOS specialty designations would result in the exclusion of certain clinician types, such as NPs and PAs (86 FR 65398). We adopted definitions of a single specialty group and a multispecialty group in the CY 2022 PFS final rule but did not finalize PECOS as the data source or specify another data source that we would use to determine a group's specialty type. We noted that we needed additional time to better understand our options to utilize different data sources when making this determination (86 FR 65399).

Having reviewed the available data sources, we believe that Medicare Part B claims data is the appropriate data source for determining a group's specialty type or types for purposes of MVP reporting. Currently, we use PECOS and Medicare Part B claims data to identify clinician specialty for certain purposes. For purposes of public reporting, we rely on PECOS as the primary data source, and for purposes of MIPS eligibility determination, we use both PECOS and claims data. Additionally, we use the information on claims to identify clinician specialty when attributing some of the measures in the cost and quality performance categories.

A clinician's primary specialty designation in PECOS is identified by the clinician in the Medicare enrollment application for physicians and non-physician practitioners. Additionally, there may be instances when a clinician would be allowed to select more than one primary specialty in PECOS.[397] For example, a primary specialty designation of cardiothoracic surgery is not available in PECOS, and therefore, a cardiothoracic surgeon would have two primary specialty designations, one for cardiac surgery and another for thoracic surgery. In such instances, it would be difficult for CMS to identify a clinician's primary specialty using their PECOS designation. The specialty codes used on Medicare Part B claims[398] are not reported by clinicians but are assigned by the Medicare Administrative Contractors (MACs) and derived from the clinician-reported specialty information in PECOS. In instances where more than one specialty code appears on a claim, we determine primary specialty based on the specialty code used for the plurality of the services billed by the clinician. We analyzed the identification of specialty for clinicians using claims data and PECOS data and found a variance rate of less than 1 percent between the two data sources. Given the strong alignment between the data sources and our historical use of claims data to identify a clinician's specialty, we believe that Medicare Part B claims data would be the best data source to use to determine a group's specialty type or types for purposes of participation in MVPs.

We note that in response to our proposal to use PECOS data in determining specialty, some commenters recommended that, instead of PECOS, CMS should utilize specialty taxonomy codes which they stated were more detailed than PECOS specialty codes (86 FR 65398). While these commenters were not specific in their request, we understood them to be referring to the provider taxonomy codes used on the application to receive a National Provider Identifier (NPI). We agree with the commenters that in some instances, the health care provider taxonomy code set may include more specificity than the information found in the specialty codes used on Medicare Part B claims. However, currently we do not use this data for other QPP purposes, and we are uncertain of the extent to which it is maintained by clinicians if their circumstances change. While we considered the use of this data as an alternative, we do not believe it is necessary to introduce a new data source at this point, given that subgroup reporting is voluntary at this time.

For these reasons, we propose to modify the definition of a single specialty group at § 414.1305 to state that single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims. We also propose to modify the definition of a multispecialty group at § 414.1305 to state that multispecialty group means a group that consists of two or more specialty types as determined by CMS using Medicare Part B claims. We seek public comment on these proposals and request comment on additional data sources CMS could use to determine a group's specialty type or types.

(3) Subgroup Registration Requirements

(a) Background

We established at § 414.1365(b) a registration process for clinicians who choose to report MVPs through a subgroup. Under this policy, a subgroup must register between April 1 and November 30 of the applicable calendar year performance period or a later date specified by CMS. A subgroup that elects to report the CAHPS for MIPS Survey[399] associated with an MVP must complete their registration by June 30 of the applicable performance period (86 FR 65416). At the time of registration, a subgroup must select an MVP on which it intends to report, and a population

[397] *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf.*

[398] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf.*

[399] OMB control number 0938–1222; Expiration date 05/31/2022 (pending re-approval).

health measure included in the foundational layer of the MVP (86 FR 65416 and 65417). Additionally, a subgroup may select an outcomes-based administrative claims measure if available in an MVP (86 FR 65417). We finalized that a subgroup must submit a list of TIN/NPIs associated with the subgroup and a plain language name for the subgroup (§ 414.1365(b)(2)(ii)). We note that we are not currently proposing any changes to the subgroup registration timeline. We refer readers to the CY 2022 PFS final rule (86 FR 65415 through 65418) for additional details on subgroup registration requirements.

(b) Subgroup Description Requirement

In the CY 2022 PFS final rule (86 FR 65399), we defined a subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. We did not propose any criteria for limiting the composition of a subgroup but did solicit comment on criteria that we could consider in the future (86 FR 39362), such as establishing a threshold requiring 75 percent of the eligible clinicians in a group or subgroup to be of the same or a related specialty to form a subgroup. In response to that request, many commenters expressed concern that single specialty subgroups may discourage team-based care and that the primary specialty designation for certain clinicians may not adequately reflect their clinical role (86 FR 65399 and 65400). Several commenters particularly pointed to the challenges associated with NPs and PAs, who are designated as an NP or a PA based on their education credentials as opposed to a clinical specialty relevant to the scope of care provided (86 FR 65399). A few commenters requested further engagement with members of the public before limiting the composition of subgroups so that CMS could better understand how clinicians work together.

We believe the comments we received reflect the reality that clinicians practice in many ways within a group TIN. While we anticipate we may need to establish requirements and/or restrictions on the composition of subgroups through rulemaking in future years, we are not proposing to establish such policies for the CY 2023 performance period/CY 2025 MIPS payment year. We believe that we may need to establish limits on subgroups in order to further our goals of measuring as many clinicians as possible using the measures that are most relevant to their practice. We are concerned that if we do not establish restrictions or requirements in the future we may not move meaningfully towards that goal. However, given that subgroups will be newly available for the CY 2023 performance period/CY 2025 MIPS payment year and will be voluntary, we do not believe we should yet establish those policies.

To inform our future subgroup policies, we desire to better understand how group TINs form subgroups and how group TINs choose to organize their subgroups. For this reason, we propose that as part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. We would identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text-only field, if the options we provide do not correctly describe the subgroup. We would not evaluate or approve the narrative description, if submitted. Rather, we intend to collect and review the information to better inform our understanding of subgroups and the different ways groups would choose to form subgroups. We believe that receiving the information about the subgroup directly from the group TIN itself would fill a gap in our understanding of the nature of subgroup formation during the transition to MVPs that cannot be filled merely by reviewing PECOS or claims-based group specialty information. We understand requiring such reporting would create some additional burden, but we believe such burden is modest and worth the effort to inform future development of subgroup policies. Furthermore, we are attempting to mitigate this burden by permitting subgroups to select from certain common scenarios for groups to form subgroups, when appropriate, instead of drafting a narrative description. We refer readers to section V.B.9.e.(7)(a) (ii) of this rule for the discussion of estimated burden related to this proposal.

We note that we are not intending for these narratives to be lengthy but expect the narratives to be short descriptions of the nature of practice and appropriately reflect the composition of a subgroup. We offer some illustrative examples for the narrative description:

- *Example 1:* This subgroup represents our cardiovascular service line, which includes cardiologists, cardiothoracic surgeons, and other associated professionals.
- *Example 2:* This subgroup represents our west side practice, which uses one electronic health record (EHR) platform and collaborates on patient care across orthopedic surgeons, physical therapists, NPs, and other associated clinicians.

We also believe that the availability of subgroups will facilitate our efforts to increase health equity. In part, we believe that by creating a smaller group of clinicians to analyze, we can better understand care at the patient and community level. This is important for measuring and improving health equity because subgroup data could be utilized to identify gaps in clinical outcomes, patient characteristics, and specialist care availability on a more targeted level than shown by examining TIN-level data. We also believe that group practices may share this same interest in improving health equity. For example, a group may have clinicians practicing in different locations and may choose to organize their subgroups to focus on certain underserved populations based on geography or income. We hope to better inform our understanding of clinicians supporting this goal through narrative descriptions of subgroup organization.

(c) Limitation of One Subgroup per TIN–NPI Combination

In the CY 2022 PFS final rule (86 FR 65414 and 65415), we finalized at § 414.1318(c)(2) that subgroups will have their performance assessed at the subgroup level across all the MIPS performance categories. Additionally, we did not propose any criteria for the composition of subgroups (86 FR 39362). We must nonetheless place some restrictions on the allocation of a group TIN's clinicians among subgroups to properly score each subgroup. Clinicians in small groups are eligible to register as subgroups and report using Medicare Part B claims. While we establish a subgroup identifier as part of the registration process, this subgroup identifier would not be present on any claims data. If we were to allow a clinician to register under more than one subgroup in a single group TIN, we would be unable to determine to which subgroup a particular claim should be connected. Therefore, we propose at § 414.1318(a)(3) that an individual eligible clinician, as represented by a TIN–NPI combination may register for no more than one subgroup within a group's TIN. We are not proposing any other restrictions or requirements on the composition of subgroups at this time.

We are also proposing to limit a clinician to a single subgroup per group TIN to overcome current limitations in

scoring certain cost and quality measures. In section IV.A.8.e.(4)(b) of this rule, we are proposing to evaluate clinicians in subgroups using measures in the cost performance category, and the population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group's performance. We are making that proposal due to current technical limitations related to attribution and risk adjustment of such measures but are working to potentially overcome those challenges in the future. CMS calculates administrative claims measures using Medicare claims data. This does not require any additional reporting by clinicians. If we were to allow a clinician to be a part of more than one subgroup within a single group TIN, however, we would be unable to identify which subgroup the clinician was part of for the purposes of attributing cost measures, population health measures, and outcomes-based administrative claims measures.

We recognize that our proposal to limit each TIN–NPI combination to a single subgroup per group TIN would limit how a group may establish its subgroups. We believe there may be clinicians who work in different capacities within a single group TIN (for example, a clinician who works in a cardiology clinic on Mondays and the primary care clinic Tuesday–Friday) which could be considered to work in multiple subgroups in a single group TIN. For this reason, we are interested in hearing perspectives from groups on how common this is, and if there are ways that we could match a clinician to a subgroup for measures reported through Medicare Part B claims or calculated using administrative claims.

(d) Subgroup Determination Period

In the CY 2022 PFS final rule, we established the definition of a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI (86 FR 65399). We also codified at § 414.1318(a) that, for a MIPS payment year, low-volume threshold criteria and special status for subgroups are determined at the group level in accordance with §§ 414.1305 and 414.1310. We also established at § 414.1365(b) a process for clinicians to register as a subgroup for the purpose of reporting the measures and activities in an MVP (86 FR 65415 through 65418). Previously, we defined a MIPS determination period—the period of activity we review to identify clinicians who are eligible to participate in MIPS—to mean, in relevant part, a 24-month assessment period consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and (2) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs (§ 414.1305; 83 FR 59727 through 59730). In order to determine their eligibility to participate in MIPS for the applicable performance year, an individual clinician or a group must meet or exceed the low-volume threshold criteria specified under § 414.1305 during the MIPS determination period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. Additionally, an individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second 12-month segment of the MIPS determination period will be assessed based solely on the results of such segment.

In the CY 2022 PFS final rule, we did not discuss how CMS would assess the low-volume threshold for individual clinicians and groups for the purpose of subgroup participation. Specifically, we did not discuss whether any special considerations were necessary when applying the MIPS determination period for clinicians participating as subgroups. Currently, we review claims and PECOS data from a MIPS determination period to determine MIPS eligibility for an individual clinician and a group. The initial 12-month segment of the MIPS determination period spans from October 1 of the calendar year 2 years prior to the applicable performance period to September 30 of the calendar year preceding the applicable performance period and includes a 30-day claims run out. Individual clinicians and groups receive their initial eligibility information prior to the applicable performance period but do not know their final eligibility determination until November or December of the applicable performance period.

Using a 2-year MIPS determination period is incompatible with the framework we have established for subgroup participation in MVPs. For example, for the CY 2023 performance period/CY 2025 MIPS payment year, individual clinicians and groups that choose to participate as subgroups would only know their preliminary eligibility at the time of subgroup registration. We believe that by using the preliminary eligibility information, clinicians and groups could assess their ability to participate as subgroups early in the performance period and we do not wish to limit subgroup participation for groups that are otherwise eligible based on an eligibility assessment that is not made until after registration is completed. Therefore, we are proposing to add at § 414.1318(a)(4) that CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the initial 12-month segment of the applicable MIPS determination period. Under this proposal, an individual eligible clinician or group determined to be MIPS eligible based on the low-volume threshold determination under § 414.1305 during the initial 12-month segment of the MIPS determination period would continue to be eligible for an applicable performance period regardless of the results of the second segment of the low-volume threshold determination. Additionally, we propose to make conforming changes at § 414.1318(a)(1) to state that, except as provided under paragraph (a)(2) of this section and subject to (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310. We note that we are not making any further changes to the application of low-volume threshold and special status as described under § 414.1318(a)(1).

In summary, to form a subgroup, a group would need to be eligible to participate in MIPS as a group and have at least one MIPS eligible clinician in the subgroup who was also a MIPS eligible clinician during the initial 12-month segment of the determination period. Such an individual eligible clinician or group would continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. A subgroup may thus include an individual clinician who does not exceed the low-volume threshold during the first segment of the MIPS determination

period only if the subgroup has at least one MIPS eligible clinician during the first 12-month segment of the MIPS determination period and the affiliated group also meets the low-volume threshold during the first 12-month segment of the MIPS determination period. We believe this would also allow practices to identify and place clinicians in appropriate subgroups, choose the measures and activities relevant to subgroups, make administrative changes to their workflows and EHR systems, and comprehensively capture clinician performance through subgroups. Using the first segment of the determination period would also be consistent with the use of the first segment of the MIPS determination period for Virtual Groups (§ 414.1315(c)(1)(*ii*); 83 FR 59743 and 59744).

We seek public comment on this proposal.

(4) Subgroup Reporting and Scoring

(a) Subgroups Reporting the APP

We refer readers to section IV.A.9.b of this proposed rule for our proposals with regard to subgroups reporting the APP.

(b) Subgroup Scores for Administrative Claims Measures and Cost Measures

In the CY 2022 PFS final rule, we established at § 414.1318(c)(2) that subgroups will have their performance assessed at the subgroup level across all the MIPS performance categories (86 FR 65414 through 65415). We also established in the quality performance category that subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available (86 FR 65421 through 65422). In establishing this policy, we noted our concern about the ability of subgroups to meet the case minimum for an administrative claims measure and our interest in including population health measures in the subgroup's score for the MVP.

In establishing our policies for scoring the cost performance category in MVPs, we received a comment that expressed concern that multi-specialty groups may take advantage of the option to report at the subgroup level to avoid being assessed on cost measures (86 FR 65422). While we intend to monitor subgroup implementation and assess the potential for gaming, we acknowledge the risk of a multi-specialty group forming subgroups in order to avoid being measured in the cost performance category.

Measures in the cost performance category, as well as population health measures (which are part of the foundational layer of MVPs) and outcomes-based administrative claims measures in the quality performance category, are not reported directly by clinicians. Instead, CMS calculates these measures based on Medicare administrative claims data. Each measure includes an attribution and risk adjustment methodology within the specifications, which are available for review at *https://qpp.cms.gov/*. These measures are created and tested for validity and reliability using Medicare administrative claims data, which includes the identification of the TIN and the clinician's NPI. However, because subgroups are established exclusively for the purpose of participation in the Quality Payment Program, we are unable to identify a subgroup using existing or future claims data, and therefore, it may not be possible to test these measures for validity and reliability for subgroups using claims data. While we believe in general that subgroups can be measured in the same manner as we measure groups, there are complications related to the establishment of subgroups. Subgroups differ from groups in a couple of key ways: First, the creation of a subgroup does not change the nature of the group, so a patient could be attributed to both a group and a subgroup. In addition, a group TIN is not required to allocate all clinicians into subgroups. This affects measures in different ways depending on the attribution methodology of a measure. For example, in the total per capita cost measure, months are attributed to a particular group TIN or TIN–NPI based on specific primary care services. In this measure, costs are assigned to a single group TIN for the purpose of measuring the group TIN and a single TIN–NPI for the purpose of measuring the TIN–NPI. We believe we could assign a patient to a single subgroup, as we have also proposed to limit NPIs to a single subgroup per TIN. However, since we do not have an existing data source for subgroup composition, we are unable to examine the data to determine if performance on the measure is reliable and valid at the subgroup level.

For these reasons, we propose to assess subgroups on measures in the cost performance category, and population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group. We propose to modify § 414.1365(d)(3)(i)(A)(*1*) to read that a subgroup is scored on each selected population health measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We also propose to add § 414.1365(d)(3)(i)(B)(*1*) so that a subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points. We also propose to add § 414.1365(d)(3)(ii)(A) to state that a subgroup is scored on each cost measure included in the MVP that they select and report based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).

We are concerned that measuring subgroups based on their affiliated group score for these measures may detract from our efforts to generate more clinically relevant and granular information about clinician performance. For this reason, we intend to pursue potential technical solutions to these issues in the future, to enable us to measure clinicians in subgroups on these measures at the subgroup level. Even if we address these technical issues, we are still concerned that clinicians may use the opportunity to form subgroups to avoid being measured on cost as discussed in the public comment we received (86 FR 65422). If we are able to address the technical limitations in the future and evaluate performance at the subgroup level, we would anticipate developing policies similar to our existing policy for population health measures to use the affiliated group score if we are unable to calculate the measures for the subgroup. This would allow us to focus our measurement at the subgroup level but limit the opportunity of groups to use the formation of subgroups to avoid being measured in the cost performance category. Since we are uncertain if we will be able to address these technical issues, we are not proposing a policy at this time.

We also believe the registration information we receive from subgroups for CY 2023 performance period/CY 2025 MIPS payment year will help us to

learn more about the nature of subgroups and better test our measures.

We seek public comment on these proposals.

(c) Scoring for Subgroups That Register But Do Not Report

As described in the CY 2022 PFS rule (86 FR 65415 through 65418), groups interested in participating as subgroups for reporting the measures and activities in an MVP must adhere to the registration process established at § 414.1365(b). To be assessed on their performance at a subgroup level, clinicians participating as subgroups would need to meet the reporting requirements outlined at § 414.1365(c). We expect subgroups to register with the intent to submit data for the measures and activities in an MVP because they wish to be assessed based on their performance at the subgroup level. We also believe there will be instances where a subgroup would register but not submit data for the applicable performance period or clinicians in a registered subgroup would choose to participate in MIPS via a different reporting option instead of reporting as a subgroup. We considered whether we should assign a score for a subgroup regardless of their submission status. At this point in time, we want to encourage groups to explore the subgroup reporting option and not penalize subgroups that do not submit data. During the voluntary years of subgroup reporting, we do not intend to assign a subgroup score in instances when we do not receive any MVP data for clinicians in registered subgroups. However, we expect that MIPS eligible clinicians in registered subgroups would participate in MIPS via another available reporting option as they would be subject to the MIPS payment adjustment under the TIN. Under the existing scoring hierarchy established in the CY 2022 PFS final rule (86 FR 65536 and 65537), a clinician is assigned the highest of the available final scores associated with the clinician's TIN/NPI.

For these reasons, we propose at § 414.1318(b)(1) that we will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period. Additionally, we propose to make conforming changes at § 414.1318(b) to state that, except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance. We intend to continue monitoring the participation trends for subgroup reporting and reevaluate scoring for registered subgroups that do not submit data as we move towards mandatory subgroup reporting in the future.

(d) Subgroup Examples

In the CY 2022 PFS final rule (86 FR 65400), we stated that during the initial years of subgroup reporting, the affiliated group will continue to include subgroup reporters in their traditional MIPS submission across all four performance categories. Additionally, we updated the scoring hierarchy to include subgroups and to specify that the scoring hierarchy will apply with respect to any available final score that is associated with a TIN/NPI from MVPs, traditional MIPS, and/or the APP (86 FR 65537). We have provided examples below to illustrate how the final score is applied for a clinician who is part of a TIN where only some of the clinicians in that TIN choose to participate in MIPS through subgroups. The MVPs used in the below examples are for illustrative purposes only and are not intended to be exhaustive of the different ways clinicians could participate in MIPS.

Scenario 1: In this example, we illustrate a TIN that is eligible as a group and includes individual MIPS eligible clinicians. For the purposes of this example, we illustrate scoring for three clinicians who are individually eligible represented by letters for simplicity. A portion of the clinicians under the TIN form one subgroup to report the measures and activities in the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP*. The TIN also forms another subgroup to report the measures and activities in the *Advancing Care for Heart Disease MVP*. The group TIN submits data for the *Optimizing Chronic Disease Management MVP. The group submission will include the performance of the clinicians in the subgroup*. The three individual MIPS eligible clinicians, clinicians A, D, and G, submit data as individuals in traditional MIPS in addition to their submissions as part of a subgroup or the group as a whole. In Table 76, we illustrate the calculated final score for their submissions at the full group, subgroup, and individual level. In Table 77, we illustrate the final scores for the individual TIN/NPI based on the existing scoring hierarchy finalized in the CY 2022 PFS final rule (86 FR 65537).

TABLE 76: Scoring Example for Participation in MIPS: Group, Subgroup, and Individual Reporting (Scenario 1)

Participation Type	What is Being Reported	Final Score
Full group (ABCDEFG)	Optimizing Chronic Disease Management MVP	90
Subgroup #1 (ABC)	Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP	80
Subgroup #2 (FG)	Advancing Care for Heart Disease MVP	97
Individual reporter (A)	Traditional MIPs	98
Individual reporter (D)	Traditional MIPS	88
Individual reporter (G)	Traditional MIPS	60

TABLE 77: Final Score for MIPS Group, Subgroup, and Individual Reporting (Scenario 1)

TIN-NPI	Full Group Final Score	Subgroup Final Score	Individual Final Score	Final Score Attributed to TIN/NPI	Reason for Final Score Attributed to TIN/NPI
A	90	80	98	98	Individual score is higher than both full group and subgroup score.
B	90	80	N/A	90	Full group score is higher than subgroup score.
C	90	80	N/A	90	Full group score is higher than subgroup score.
D	90	N/A	88	90	Full group score is higher than individual score – no subgroup score.
E	90	N/A	N/A	90	Only full group score is available.
F	90	97	N/A	97	Subgroup score is higher than full group score.
G	90	97	60	97	Subgroup score is higher than full group score and individual score.

Scenario 2: In contrast to scenario 1, in this example, we illustrate final scoring for a TIN when a portion of the clinicians under the TIN form one subgroup for reporting an MVP and the whole TIN participates as a group only for reporting traditional MIPS. Similar to scenario 1, the TIN is eligible as a group and includes individual eligible clinicians. We note that the TIN does not participate as a group for MVP reporting. For the purposes of this example, we illustrate scoring for three clinicians who are individually eligible represented by letters for simplicity. A portion of the clinicians under the TIN form only one subgroup to report the measures and activities in the *Advancing Care for Heart Disease MVP*. The group TIN submits data for traditional MIPS. *The group submission will include the performance of the clinicians in the subgroup*. The three individual MIPS eligible clinicians, clinicians A, D, and G, submit data as individuals in traditional MIPS in addition to their submissions as part of the subgroup or the whole group. In Table 78, we illustrate the calculated final score for their submissions at the full group, subgroup, and individual level. In Table 79, we illustrate the final scores for the individual TIN/NPI based on the existing scoring hierarchy finalized in the CY 2022 PFS final rule (86 FR 65537).

TABLE 78: Scoring Example for Participation in MIPS: Group, Subgroup, and Individual Reporting (Scenario 2)

Participation Type	What Is Reported	Final Score
Full group (ABCDEFG)	Traditional MIPS	90
Subgroup (FG)	Advancing Care for Heart Disease MVP	97
Individual reporter (A)	Traditional MIPS	98
Individual reporter (D)	Traditional MIPS	88
Individual reporter (G)	Traditional MIPS	60

TABLE 79: **Final Score for MIPS Group , Subgroup, and Individual Reporting (Scenario 2)**

TIN-NPI	Full Group Final Score	Subgroup Final Score	Individual Final Score	Final Score Attributed to TIN/NPI	Reason for Final Score Attributed to TIN/NPI
A	90	N/A	98	98	Individual score is higher than full group score.
B	90	N/A	N/A	90	Full group score, no other scores available.
C	90	N/A	N/A	90	Full group score, no other scores available.
D	90	N/A	88	90	Full group score higher than individual score
E	90	N/A	N/A	90	Full group score, no other scores available
F	90	97	N/A	97	Subgroup score higher than full group score
G	90	97	60	97	Subgroup score higher than full group score and individual score

Scenario 3: In contrast to scenarios 1 and 2, in this scenario, we illustrate final scoring for a TIN that does not participate as group. Similar to scenarios 1 and 2, we have a TIN that is eligible as a group and includes individual eligible clinicians. In this scenario, a portion of the clinicians under the TIN form two subgroups for reporting an MVP and the TIN does not submit data at the group level. For the purposes of this example, we illustrate scoring for three clinicians who are individually eligible represented by letters for simplicity. A portion of the clinicians under the TIN form one subgroup to report the measures and activities in the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP*. The TIN also forms another subgroup to report the measures and activities in the *Optimizing Chronic Disease Management MVP*. Three individual MIPS eligible clinicians, clinicians A, D, and G, submit data as individuals in traditional MIPS in addition to their submissions as part of a subgroup. In Table 81, we illustrate the calculated final score for their submissions at the full group, subgroup, and individual level. In Table 81, we illustrate the final scores for the individual TIN/NPI based on the existing scoring hierarchy finalized in the CY 2022 PFS final rule (86 FR 65537).

TABLE 80: **Scoring Example for Participation in MIPS: Subgroup and Individual Reporting ; No Group Reporting (Scenario 3)**

Participation Type	What is Reported	Final Score
Full group (ABCDEFG)	No submission	N/A
Subgroup #1 (ABC)	Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP	80
Subgroup #2 (FG)	Optimizing Chronic Disease Management MVP	97
Individual reporter (A)	Traditional MIPS	98
Individual reporter (D)	Traditional MIPS	88
Individual reporter (G)	Traditional MIPS	60

TABLE 81: Final Score for MIPS Subgroup and Individual Reporting; No Group Reporting (Scenario 3)

TIN-NPI	Full Group Final Score	Subgroup Final Score	Individual Final Score	Final Score Attributed to TIN/NPI	Reason for Final Score Attributed to TIN/NPI
A	N/A	80	98	98	Individual score higher than subgroup score
B	N/A	80	N/A	90	Subgroup score
C	N/A	80	N/A	90	Subgroup score
D	N/A	N/A	88	88	Individual score only available
E	N/A	N/A	N/A	N/A	Not eligible as individual and no group submission so does not receive score
F	N/A	97	N/A	97	Subgroup score
G	N/A	97	60	97	Subgroup score higher than individual score

9. APM Performance Pathway

a. Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in performance year 2021, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation.

b. APP Reporting Options

Under the APP, MIPS eligible clinicians in an APM Entity that participates in a MIPS APM may report to MIPS and be scored (subject to certain limitations) at the individual clinician, group, or APM Entity level (85 FR 84859 through 84866).[400] [401] In that rule, we excluded Virtual Groups from reporting the APP. At that time, the concept of MIPS Value Pathway (MVP) subgroup reporting, through which a subset of MIPS eligible clinicians within a group TIN may report and be scored as a standalone MVP Participant, had not yet been introduced; however, we note that our subsequent use of the term ''subgroup'' may have caused confusion in light of its use in MVPs. In the CY 2022 PFS final rule, we codified policies related to subgroups at § 414.1318 (86 FR 65671), by which we meant the reporting of the APP by a subset of MIPS eligible clinicians within an APM Entity. In that rule, we stated that because we already identify the MIPS eligible clinicians who are MIPS APM participants based on Participation Lists for each APM, it is unnecessary to require MIPS APM participants to register as subgroups for purposes of reporting the APP (86 FR 65397 and 65398). We stated that beginning with performance year 2023, we will use Participation Lists to identify the MIPS eligible clinicians within a group TIN that should be included in the subgroup of APM participants for purposes of reporting the APP (86 FR 65398). We also codified at § 414.1318(c)(2) that subgroups would be scored according to the applicable MVP or APP scoring rules. However, under § 414.1367, which governs APP reporting and scoring, no changes were made to reflect the introduction of subgroup-level reporting of the APP.

Recognizing that there is ambiguity in our current rules, we are proposing to modify the text at § 414.1318(c)(2) to remove the reference to subgroup scoring of the APP, and therefore, disallow reporting of the APP by a subset of a group. This proposed change is not intended as a change in policy; as described previously in this section of the proposed rule, it was not our intent to permit MIPS eligible clinicians within an APM entity to be scored at a level in between a group and the individual clinician.

Notwithstanding the foregoing, we recognize that MIPS eligible clinicians may have an interest in reporting as subgroups in the APP, and as we describe further later in this section of the propose rule, we are considering as an alternative to our above proposed conforming change whether to permit subgroups as a level of reporting the APP, and to modify § 414.1367 accordingly. We believe there could be scenarios where a group may have an interest in reporting the APP through subgroups. For example, if a large multi-specialty TIN had specialists of different types participating in MIPS APMs, and, therefore, who are eligible for APP scoring, it would be possible that a subgroup within that TIN—perhaps primary care providers working out of a single EHR or practice site—would be interested in reporting the APP using only the data generated by MIPS eligible clinicians in that subgroup. Additionally, particularly after MVP reporting is more widely performed, we recognize that clinicians using subgroup reporting for MVPs may have an easier time joining APMs and reporting the APP if they are able to maintain their reporting at the same level, thereby strengthening MVPs as a glide path to APM participation.

To permit subgroup reporting of the APP, we would need to enable a subgroup registration option for APP reporters, which would inevitably introduce additional administrative burden for the subgroups that would report. Aside from needing to register in order to be recognized as a subgroup, all other aspects of APP reporting for subgroups under this alternative proposal would be the same as for other reporting levels as established at § 414.1367. We request comments on the proposed conforming change and the alternative we considered. In particular, we are interested in commenters' input from the public on which option would best balance the reporting flexibilities with administrative burdens, with the understanding that it may be necessary to revisit these policies in future rulemaking as MVP and APP policies continue to develop, we seek comment on this proposal.

10. MIPS Performance Category Scoring

a. Quality Performance Category

As discussed in section III.J.4 and elsewhere in this proposed rule, we are

[400] Paperwork Reduction Act: CMS–10621, OMB 0938–1314.

[401] In that rule, we excluded Virtual Groups from reporting via the APP.

seeking comment on the potential addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions.

In this proposed rule, we are seeking feedback on the potential future inclusion of two new measures in the APP measure set: MUC21–136: Screening for Social Drivers of Health and MUC21–134: Screen Positive Rate for Social Drivers of Health. The National Quality Forum (NQF) provided conditional support for these two social determinants of health measures during the 2021–2022 cycle and indicated the measures would be appropriate for consideration in the Shared Savings Program.[402] The measure MUC21–136: Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for health-related social needs, which is consistent with the priorities of the agency and program including Meaningful Measures 2.0 priority areas.[403] The measure MUC21–134: Screen Positive Rate for Social Drivers of Health assesses the percentage of patients who screened positive for health-related social needs.

We encourage readers to review the Social Determinants of Health Measure and Future Measure Development—Request for Information (RFI) discussed at section III.J.4. of this proposed rule.

b. Improvement Activities Performance Category

Section 414.1367(c)(3) provides that the improvement activities performance category score for MIPS eligible clinicians, groups, and APM Entities reporting via the APP is calculated in accordance with § 414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities. We assign scores to each MIPS eligible clinician in the improvement activity performance category for participating in MIPS APMs, and MIPS eligible clinicians must earn 40 points in order to receive full credit in this performance category. On an annual basis, we conduct a review of the governing documentation of all MIPS APMs to determine the Improvement Activities that are required by each such APM, and have in all cases found that each MIPS APM requires participants to engage in such Improvement Activities as would earn participants a performance category score of no less than 40 points, which as discussed previously in this section of the propose rule is the maximum score for this performance category (§ 414.1380(a)(1)(iii)). The list of required activities for each MIPS APM is compared to the MIPS list of improvement activities and the MIPS APM's participants that report the APP are scored in accordance with MIPS to determine if the APM meets the requirements for awarding full credit (40 points) for Improvement Activities to the participants in the MIPS APM.

We would like to clarify that, even though § 414.1367(c)(3) permits the reporting of additional improvement activities, such reporting would not supersede the automatic award of the maximum score described previously in this section of the proposed rule. Because the reporting of additional improvement activities does not serve any Improvement Activity scoring purpose, we would not use any Improvement Activity performance category submissions for scoring under the APP where the participants were already entitled to full credit for this performance category. This clarification is particularly relevant in instances where an APM Entity is eligible for reweighting of the two remaining performance categories of quality and promoting interoperability. We understand it is possible that, for example, a data submission from the Application Programming Interface (API) of a TIN or individual within an APM Entity could contain incidental Improvement Activity performance information that was collected automatically, though not for the purpose of a MIPS submission or scoring. We clarify that the submission of Improvement Activity performance information in this type of circumstance would not constitute a submission of data for the purpose of scoring the improvement activities performance category under the APP. Therefore, incidental submissions such as the type in this example would never be the sole basis for an APM Entity to be scored under the APP.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, and 86 FR 65431 through 65445, respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In this proposed rule, we are proposing to:

- Amend the definition of the term ''high priority measure'' to include quality measurement pertaining to health equity.
- Replace the ''Asian language survey completion'' variable with ''language other than English spoken at home'' variable in the case-mix adjustment model for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey.
- Increase the data completeness criteria threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.
- Modify the MIPS quality measure set as described in Appendix 1 of this final rule, including through the addition of new measures, updates to specialty sets, the removal of existing measures, and substantive changes to existing measures.

(b) Quality Data Submission Criteria

(i) Submission Criteria for Quality Measures, Excluding the CAHPS for MIPS Survey Measure

The Meaningful Measures Initiative provides for the identification of high priority areas for quality measurement and quality improvement, which identifies the core quality of care issues that advances our work to improve patient outcomes (83 FR 59719). In order to further identify priority areas for MIPS quality measurement, we defined the term high priority measure at § 414.1305, for years beginning with the CY 2019 performance period/2021 MIPS payment year, as an outcome (including intermediate-outcome and

[402] *https://www.qualityforum.org/setting_priorities/partnership/map_final_reports.aspx.*

[403] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure (83 FR 59761). Generally, if an applicable outcome measure is not available, a MIPS eligible clinician must report a high priority measure (§ 414.1335(a)(1)). To incentivize the voluntary adoption of high priority measures, a MIPS eligible clinician may earn bonus points for reporting such a measure (§ 414.1380(b)(1)(v)(A)). As significant and persistent inequities in healthcare outcomes exist in the United States, we are committed to developing innovative solutions that support access to high quality care and promote health equity, including the exploration of solutions to measure health equity within MIPS. Health equity is a priority area across CMS programs, including MIPS.

Thus, we are proposing to amend the definition of the term high priority measure to include health equity measures. Specifically, starting with the CY 2023 performance period, we are amending the definition of the term high priority measure at § 414.1305 to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. We believe that it is imperative to include quality measures pertaining to health equity as high priority measures in order to incentivize the adoption of health equity measures by MIPS eligible clinicians.

We seek public comment on our proposal to amend the definition of the term high priority measure.

(ii) Submission Criteria for the CAHPS for MIPS Survey Measure

The CAHPS for MIPS Survey measures patients' experience of care within a group, virtual group, and APM Entity, including Shared Savings Program ACOs. The survey measures ten dimensions of patient experience of care, known as summary survey measures, for which patients may be the best, if not only source of information. The CAHPS for MIPS Survey is optional for all groups, virtual groups, and APM Entities of 2 or more eligible clinicians reporting via traditional MIPS, and is required for Shared Savings Program ACOs reporting via the APM Performance Pathway (APP).

(A) CAHPS for MIPS Survey Measure Case-Mix Adjustment Model

Under the CAHPS for MIPS Survey measure, we adjust summary survey measure scores for case-mix to promote meaningful comparison of the performance of MIPS groups despite differences in their patient populations (81 FR 77120). The case-mix adjustment model for CAHPS for MIPS Survey measure includes the following case-mix adjustors as of the CY 2022 performance period: age; education; self-reported general health status; self-reported mental health status; proxy response; Medicaid dual eligibility; eligibility for Medicare's low-income subsidy; and Asian language survey completion (86 FR 65444 and 65445).

Only a small percentage of CAHPS for MIPS Survey participants who report speaking a language other than English at home actually complete the survey in that language. We believe that collecting information on the language spoken by the participant at home as a case-mix adjustor rather than the language used by the respondent to complete the survey is likely to capture language preference more accurately, as well as response patterns of participants with similar experiences, for a more meaningful comparison of performance between MIPS groups. Furthermore, more accurately capturing preferred language aligns with CMS's effort to provide culturally and linguistically appropriate services (CLAS), which are intended to advance health equity, improve quality, and help eliminate health care disparities.[404] Other CMS-administered CAHPS Surveys, such as the CAHPS for Hospice Survey and the Hospital CAHPS Survey, include preferred language variables rather than survey language variables for case-mix adjustment. Furthermore, analysis of CY 2019 performance period for CAHPS for MIPS Survey measure data found that adding case-mix adjustors for Spanish language spoken at home, Asian language(s) spoken at home, and other language spoken at home has minimal impacts on scoring for most groups, and slightly positively impacts the scores of groups with substantial patient populations who speak a language other than English at home. Therefore, we are proposing to revise the CAHPS for MIPS Survey measure case-mix adjustment model to remove the existing adjustor for Asian language survey completion and to add adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home.

We seek public comment on our proposal to revise the CAHPS for MIPS Survey measure case-mix adjustment model.

(aa) Adding Items Related to Health Disparity and Price Transparency to the CAHPS for MIPS Survey Measure

We are interested in gathering information directly from patients related to health disparities and price transparency. In section III.G.4.g. of this proposed rule, we discuss the request for information regarding the future consideration of additional and modified questions related to health disparities and price transparency to the CAHPS for MIPS Survey measure. Specifically, we are seeking public comment on the following items in the request for information as outlined in section III.G.4.g. of this proposed rule: (1) the potential future inclusion of health disparities and price transparency questions and whether there are other questions that should be considered for potential future inclusion in the CAHPS for MIPS Survey measure; and (2) the potential for creating a shortened version of the CAHPS for MIPS Survey measure such that it would be more applicable to specialty groups. Therefore, we refer readers to section III.G.4.g. of this proposed rule for further information regarding this request for information.

(iii) Data Completeness Criteria

In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), the data completeness criteria threshold was established to reflect a threshold of at least 50 percent (81 FR 77125). The data completeness criteria threshold increased from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and was maintained at a threshold of at least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, the data completeness criteria threshold was increased from at least 60 percent to at least 70 percent (84 FR 62952). The data completeness criteria threshold of at least 70 percent was maintained for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). We continue to believe that it is important to incrementally

[404] Centers for Medicare & Medicaid Services. Achieving Health Equity. Available at *https://www.cms.gov/Outreach-and-Education/MLN/WBT/MLN1857916-OMH-AHE/OMHAHE/ahe/lesson01/09/index.html.*

increase the data completeness criteria as MIPS eligible clinicians, groups, and virtual groups gain experience with MIPS.

We believe that the incorporation of higher data completeness thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevent selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, and 86 FR 65436). We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632 and 86 FR 65436). The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632 and 86 FR 65436).

We previously noted concerns raised regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, and 84 FR 62951). We want to ensure that an appropriate, yet achievable, data completeness threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period (as outlined in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76), we believe that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold without jeopardizing their ability to participate and perform well under MIPS.

We are now proposing to raise the data completeness criteria from 70 percent to 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. Specifically, we propose in § 414.1340(a)(4) that, for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, a MIPS eligible clinician or a group submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs must submit data on at least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer. Similarly, we are proposing in § 414.1340(b)(4), for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, that a MIPS eligible clinician or a group submitting quality measures data on Medicare Part B claims measures would need to submit data on at least 75 percent of the MIPS eligible clinician or group's patients seen during the corresponding performance period to which the measure applies. We believe that increasing the data completeness criteria threshold to 75 percent for the CY 2024 performance period/2026 MIPS payment year and the CY 2025 performance period/2027 MIPS payment year provides MIPS eligible clinicians with ample time prepare for a higher standard as most clinicians already meet or exceed this standard.

We seek public comment on our proposal to increase the data completeness criteria threshold from at least 70 percent to at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

(c) Selection of MIPS Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding to the list, as appropriate, new measures; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2022 PFS final rule (86 FR 65687 through 65968); CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality measure set, as described in Appendix 1 of this proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2023 performance period, we are proposing a measure set of 194 MIPS quality measures in the inventory.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2023 performance period and future years can be found in Table Group A of Appendix 1 to this proposed rule. For the CY 2023 performance period, we are proposing 9 new MIPS quality measures, which includes 1 administrative claims measure; 1 composite measure; 5 high priority measures, and 2 patient-reported outcome measures).

In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. We are proposing modifications to existing specialty sets and new specialty sets as described in Table Group B of Appendix 1 to this proposed rule. Specialty sets may include: new measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 3, 2022, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 7 of MIPS under the Quality Payment Program.[405] These recommendations were based on the MIPS quality measures finalized in the CY 2021 PFS final rule and the 2021 Measures Under Consideration List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are being proposed in this proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for measure removal. We have previously specified certain criteria that will be used when

[405] Message to the Quality Payment Program listserv on January 3, 2022, entitled: ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2023 Performance Year of the Merit-based Incentive Payment System (MIPS).''

we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959). For the CY 2023 performance period, we are proposing to remove 15 MIPS quality measures and partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. We refer readers to Table Group DD of Appendix 1 of this proposed rule for further information regarding the proposals to retain such measures for retention for use in relevant MVPs. Of the 15 MIPS quality measures proposed for removal, the following pertains to such measures: 1 MIPS quality measure is duplicative to a proposed new MIPS quality measure; 4 quality measures are duplicative of current measures; 7 MIPS quality measures that do not align with the Meaningful Measure Initiative (that is, measures that are unable to produce a benchmark or have limited adoption, or are a standard of care); 2 MIPS quality measures that are under the topped out lifecycle; and 1 measure is extremely topped out. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (83 FR 59763 through 59765). We noted our belief that our proposal to remove the quality measures outlined in Table Group C of this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria.

Also, we are proposing substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 and 65442). We are proposing substantive changes to 75 MIPS quality measures, which includes 2 quality measures proposed to be retained for utilization under MVPs (we refer readers to Table Group DD of Appendix 1 of this proposed rule for such measures that are proposed for retention for use in relevant MVPs). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive.

Lastly, we are proposing substantive changes to CMS Web Interface measures that are available as a collection and submission type for Medicare Shared Savings Program ACOs meeting reporting requirements under the APP. The substantive changes to the CMS Web Interface measures can be found in Table Group E of Appendix 1 of this proposed rule. Also, in section III.G.4.c.(2) of this proposed rule, the establishment of CMS Web Interface benchmark policies for the APP under Medicare Shared Savings Program are being proposed, in which the establishment of such benchmark policies for the APP (at § 425.512) would be applied retroactively starting with the CY 2022 performance year. The CMS Web Interface benchmark policies previously established at § 425.502(b) under the Medicare Shared Savings Program were revised in the CY 2021 PFS final rule, in which the provisions under § 425.502(b) were sunset with the CY 2020 performance year and not applied to the APP under the Medicare Shared Savings Program. For performance year CY 2021, it was noted in the CY 2021 PFS final rule that the CMS Web Interface measure benchmarks developed for the Medicare Shared Savings Program for performance year CY 2020 would be utilized (85 FR 84724). However, as a result of the inadvertent failure to consider the policies that would apply for purposes of establishing benchmarks for the CMS Web Interface measures applicable to the APP starting with performance year CY 2022, benchmarks policies for the CMS Web Interface measures were not established for the APP under the Medicare Shared Savings Program. We note that the absence of benchmark policies for the APP under the Medicare Shared Savings Program impacts MIPS. The CMS Web Interface measure benchmarks established for the Medicare Shared Savings Program are utilized for purposes of MIPS (§ 414.1380(b)(1)(ii)(B)). Due to the absence of benchmark policies for the APP under the Medicare Shared Savings Program, CMS Web Interface measure benchmarks are not able to be established starting with performance year 2022. As outlined in section III.G.4.c.(2) of this proposed rule, the establishment of CMS Web Interface benchmark policies for the APP under Medicare Shared Savings Program are being proposed, in which the retroactive adoption of benchmark policies previously established at § 425.502(b) would be applied for performance year CY 2022 (and future performance years as applicable under the Medicare Shared Savings Program). Thus, for the CY 2022 performance period/2024 MIPS payment year (last year in which the CMS Web Interface is available as a collection and submission type under traditional MIPS for groups, virtual groups, and APM Entities), the CMS Web Interface benchmarks created for the APP under the Medicare Shared Savings Program would be utilized under MIPS.

We are requesting public comment on our proposals to modify the quality performance category measure set.

(i) Screening for Social Drivers of Health Proposed Measure

Established evidence demonstrates that factors beyond the clinical realm are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[406] [407] Specifically, social risk factors account for 50 to 70 percent of health outcomes.[408] [409] [410] Indeed, the Physicians Foundation surveyed 8,500 physicians in 2018 and found that almost 90 percent of respondents reported their patients had a serious health problem linked to poverty or other social conditions.[411]

Health-related social needs (HRSNs), which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[412] In

[406] Zhang, Y., Li, J., Yu, J., Braun, R.T., Casalino, L.P. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open. 2021;4*(6):e2113212. *doi:10.1001/jamanetworkopen.2021.13212.*

[407] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA, 324*(10), 975–983. Available at *https://doi.org/10.1001/jama.2020.13129.*

[408] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[409] Khullar, D. (September, 2020). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care Team-Based Approach for Advancing Health Equity.

[410] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.*

[411] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints*.pdf.

[412] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs

Continued

2017, the CMS Innovation Center launched the Accountable Health Communities (AHC) Model to test the impact of addressing the HRSNs of Medicare and Medicaid beneficiaries.[413] [414] [415] [416] Although there are other models of care that address HRSNs, the AHC Model is one of the first Federal pilots to test whether systematically identifying and addressing core HRSNs—through screening, referral, and community navigation—improves healthcare costs, utilization, and outcomes.[417] Moreover, as described in the CMS Equity Plan for Improving Quality in Medicare, complex interactions among individual need, clinician practice/behavior, and availability of community resources significantly impact healthcare access, quality, and ultimately costs.[418] [419]

Conceptually, HRSNs exist along a continuum with other equity-related terms—such as ''social determinants of health'' and ''social risk factors''—used to describe upstream factors that can adversely affect the health of individuals and communities. Often conflated and even used interchangeably, the variety of terms has created both confusion as well as concern, prompting leaders in the field to adopt ''drivers of health'' (DOH) instead.[420] Hereafter, we utilize DOH terminology to more holistically capture aforementioned and related concepts, while minimizing potential misinterpretation and/or negative connotation.

We believe that consistently addressing DOH will have two significant benefit for MIPS. First, because DOH disproportionately impact individuals and communities that are disadvantaged and/or underserved by the healthcare system, the promotion of screening for these factors would support clinician practices and health systems in actualizing an expressed commitment to address disparities in care, implementing associated equity measures to track progress, and improving overall health equity.[421]

Second, patient-level DOH data through screening is essential in the long-term to encourage meaningful collaboration among clinicians and community-based organizations, and implement and evaluate related innovations in healthcare and social service delivery.

As a first step towards addressing DOH to close health equity gaps among patients served by MIPS-eligible clinicians, we propose the adoption of an evidence-based DOH measure (we refer readers to Table Group A.3 of Appendix 1 to this proposed rule for the proposed measure information) that would support identification of specific DOH associated with inadequate healthcare access and adverse health outcomes among patients. We note that the measure would enable systematic collection of DOH data. This standardized measure would enable clinicians to systematically address DOH affecting individual patients; thereby, improving not only early identification of risk and/or need, but also prompt referral to relevant resources as well as stronger clinical-community linkages. Further, collecting DOH data could promote more focused collaboration between clinicians/health systems and appropriate community-based organizations to guide cross-sector resource allocation and ultimately improved patient outcomes.

The ''Screening for Social Drivers of Health'' measure assesses the percent of patients who are 18 years or older screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety. Under our Meaningful Measures Framework,[422] the measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close equity gaps and promote health equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [423] The development and proposal of this measure also aligns with the CMS strategic pillar to advance health equity by addressing the health disparities that underlie our health system [424] and the 5 CMS health equity priorities for reducing disparities in health: [425]

- *Priority 1:* Expand the Collection, Reporting, and Analysis of Standardized Data.
- *Priority 2:* Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps.
- *Priority 3:* Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities.
- *Priority 4:* Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services.
- *Priority 5:* Increase All Forms of Accessibility to Health Care Services and Coverage.

(d) MIPS Quality Performance Category Health Equity Request for Information

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or

Screening Tool: Promising Practices and Key Insights. June 2021. Available at *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[413] Centers for Medicare & Medicaid Services. (June, 2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[414] Alley, D.E., Asomugha, C.N., Conway, P.H., & Sanghavi, D.M. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine 374*(1):8–11. Available at *https://doi.org/10.1056/NEJMp1512532.*

[415] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives, 7*(5). Available at *https://doi.org/10.31478/201705b.*

[416] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at *https://innovation.cms.gov/innovation-models/ahcm.*

[417] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[418] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[419] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[420] ''What We Need To Be Healthy—And How To Talk About It,'' Health Affairs Blog, May 3, 2021. doi:10.1377/hblog20210429.335599. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20210429.335599/.*

[421] American Hospital Association. (December, 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[422] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[423] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[424] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[425] Centers for Medicare & Medicaid Services, CMS Framework for Health Equity 2022–2032. Available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

ethnic minoritized group; being a member of a religious minority; living with a disability; being a member of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level is often associated with worse health outcomes.[426] [427] [428] [429] [430] [431] [432] [433] [434]

One approach being employed to reduce health inequity across CMS programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. In the CY 2023 IPPS/LTCH PPS proposed rule (87 FR 28570 through 28576), there is a Request for Information regarding the Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs, which describes key considerations that we believe should be accounted for across all CMS quality programs, including MIPS, when advancing the use of measure stratification to address healthcare disparities and advance health equity across our programs. We refer readers to the CY 2023 IPPS/LTCH PPS proposed rule for further information regarding this Request for Information).

To facilitate efforts to reduce health inequities, we are considering the development of broadly applicable health equity measures for potential use within traditional MIPS and MVPs. As noted in section IV.A.10.c.(1)(d) of this proposed rule, we are proposing one health equity measure for purposes of MIPS, ''Screening for Social Drivers of Health,'' while other CMS programs are proposing two health equity measures, ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health,'' as proposed in the CY 2023 IPPS/LTCH PPS proposed rule (87 FR 28498 through 28506). As we consider the possible future inclusion of additional health equity measures in MIPS in future years (may include, but not limited to, a measure similar to the MUC2021–134 Screen Positive Rate for Social Drivers of Health measure included on the 2021 Measures Under Consideration (MUC) List),[435] we seek public comment on the following questions in order to better understand the type and structure of health equity measures that would be appropriate for the implementation in MIPS.

- How would a measure best capture health equity needs under MIPS in the future ?
- How would a measure's quality action provide actionable information and link to improvement in the quality of care provided to populations with health inequities? Would a measure be meaningful to clinicians in small practices or Federally Qualified Health Centers that may have limited or no access to referral services?
- What, if any, would be the limitations in data interpretation if a future health equity-related measure would not be risk-adjusted?
- Would there be any concerns if a future health equity-related measure did not specify requirements for use of consistent tool(s) for data collection under such a measure? Should such a future measure support flexibility in choice of tools while requiring standardized coding of responses to support interoperability?

Also, we seek public comment on the following two potential approaches for measuring health equity in MIPS and MVPs: assessing the collection and use of self-reported patient characteristics; and assessing patient-clinician communication.

(i) Assessing the Collection and Use of Self-Reported Patient Characteristics

A prerequisite for measuring and reporting quality for patients with social risk factors (that is, stratifying quality measures by patient characteristics) is collecting standardized, complete, and accurate patient data. These data include patient demographics and social drivers of health (referred to as ''patient characteristics''), which are not routinely or systematically collected across the health care system.[436] [437] We are considering ways to encourage clinicians to collect social risk information, including through the development of a measure that tracks the completeness of self-reported patient characteristics such as race, ethnicity, preferred language, gender identity, sexual orientation, disability status, income, education, employment, food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. Patient-reported data are considered to be the gold standard for evaluating quality of care for patients with social risk factors.[438]

We seek public comment on the following questions in order to understand the feasibility and usefulness of a measure that promotes the collection of self-reported patient characteristics data to provide potential opportunities for the use of patient characteristics data to understand the status of health and health care equity.

- Which self-reported patient characteristics, including but not limited to those listed above, are important to collect in a standardized format to facilitate future use in quality measures, such as stratification? Which characteristics would you consider lower priority for CMS to collect for use in quality measurement?
- Are there certain characteristics that are important to collect together to more meaningfully categorize patient populations (for example, examining the

[426] Joynt, K.E., Orav, E., & Jha, A.K. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7):675–681.

[427] Vu, M., et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *J Womens* Health *(Larchmt)* 25(6): 586–93.

[428] Lindenauer, P.K., Lagu, T., Rothberg, M.B., et al. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *British Medical Journal,* 346.

[429] Trivedi, A.N., Nsa, W., Hausmann, L.R.M., et al. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine,* 371(24):2298–2308.

[430] Polyakova, M., et al. (2021). Racial Disparities in Excess All-Cause Mortality During the Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2): 307–316.

[431] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *Rural Health Research Recap.* Available at *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[432] U.S. Department of Health and Human Services, Office of the Secretary, HHS Office of Minority Health. Progress Report to Congress. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. FY 2020. Available at *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[433] Heslin, K.C., & Hall, J.E. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. Morbidity and Mortality Weekly Report (MMWR*), 70*(5):149–154. Centers for Disease Control and Prevention. February 5, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm?s_cid=mm7005a1_w.*

[434] Poteat, T.C., Reisner, S.L., Miller, M., Wirtz, A.L. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. *medRxiv* [Preprint]. 2020 Jul 24:2020.07.21.20159327. doi:10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[435] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2021. Available at *https://www.cms.gov/files/document/overview-2021-muc-list-20220308-508.pdf.*

[436] CMS Health Services Advisory Group. (2021). CMS Quality Measure Development Plan 2020 Population Health Environmental Scan and Gap Analysis Report for the Quality Payment Program.

[437] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. (June 2020). Second Report to Congress on Social Risk Factors and Medicare's Value-Based Purchasing Program. Available at *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs.*

[438] Jarrín, O.F., Nyandege, A.N., Grafova, I.B., Dong, X., & Lin, H. (2020). Validity of Race and Ethnicity Codes in Medicare Administrative Data Compared with Gold-Standard Self-Reported Race Collected During Routine Home Health Care Visits. Med Care. 58(1): e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

intersection of race and gender identity)?

- How important is it to use a standardized tool with coded questions and data elements to collect self-reported patient characteristics across clinicians and practices and what challenges and limitations present without use of a coded and standardized instrument?
- Would the use of a consistent screening tool(s) to collect social drivers of health information improve our ability to meaningfully compare performance across clinicians, such as performance on a measure assessing referrals for identified social needs or if measures are stratified based on identified needs? How are clinicians collecting and using this type of health information to inform clinical care?
- What is a meaningful approach for monitoring improvement in standardized collection of self-reported patient characteristic data while minimizing reporting burden?
- In addition to quality measures, cost measures, and improvement activities applicable to the clinical aspect of an MVP, each MVP includes a foundational layer of population health and promoting interoperability measures, broadly applicable to most, if not all, clinicians. Is the proposed quality measure, ''Screening for Social Drivers of Health,'' appropriate for use in the foundational layer of MVPs (we refer readers to section IV.A.10.c.(1)(d) and Table Group A of Appendix 1 of this proposed rule for the proposed measure)? If so, then such inclusion would require most or all eligible clinicians to screen for social drivers of health during patient encounters.
- Is it appropriate to develop a quality measure to assess clinician referrals to community-based services upon screening positive for a social driver of health, including food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety?

We are interested in understanding differences in clinician's performance on MIPS measures for different patient populations. We understand that patient outcomes, especially for those patients who belong to underserved communities, may be influenced by factors outside of the clinician's control. We seek public comment on the following question. Would it be beneficial to: stratify either outcome or process measures by patient demographics; and/or stratify either outcome or process measures by identified social needs, such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety?

(ii) Assessing Patient-Clinician Communication

Effective communication is critical to ensuring mutual clinician-patient understanding, empowering patients, and providing high-quality care across all patient care settings and clinician types. Reliance on unqualified individuals to interpret medical information can lead to misunderstandings, devastating outcomes, or even death.[439] [440] To promote access to care for patients in need of foreign language services, we developed the Guide to Developing a Language Access Plan [441] in February of 2018. The Guide to Developing a Language Access Plan outlines steps organizations can take to provide high-quality and appropriate language assistance services to all individuals they serve. While resources are available, currently, there are not clinician-level measures in MIPS that assess the receipt of language services.[442] We are considering the development of a patient-reported outcome measure that assesses the receipt of appropriate language services and/or the extent of clinician-patient communication. We are seeking feedback on the feasibility and usefulness of such a measure(s).

If we developed such measure(s), it may be considered for the foundational layer of MVPs, meaning this measure would be required of most, if not all, eligible clinicians. Given the variance in patient needs and organizational resources, we are seeking feedback on the appropriateness of requiring all clinicians to report on such measure(s).

(e) Developing Quality Measures That Address Amputation Avoidance in Diabetic Patients Request for Information

Diabetes affects 34 million, or 13 percent, of adults in the United States. A serious potential complication of diabetes is lower extremity amputation (LEA), resulting from peripheral neuropathy (nerve damage), peripheral arterial disease (PAD, reduced blood flow to the extremities), or both. Patients with neuropathy or PAD are vulnerable to developing ulcers on the feet, which, if they become infected and do not heal, can lead to amputation. LEAs occur at a rate of 5.6 per 1000 persons with diabetes, affecting approximately 130,000 patients in 2016,[443] and evidence indicates that amputations are on the rise.

The COVID–19 pandemic has likely accelerated rates of amputation, due in part to delayed wound care and preventive care.[444] [445] LEA has devastating consequences for a patient's health and quality of life; [446] the 5-year mortality rate following LEA is estimated at 50 percent.[447] There are known disparities in LEA, with rates of amputation substantially higher among Black, Native American, and Hispanic patients as compared to White non-Hispanic patients.[448] [449] Evidence indicates that there may be gaps in care for certain populations, which contribute to these disparities.[450] For

[439] The Colorado Trust. (2013). How Language Access Issues Affect Patients, Policymakers, and Health Care Providers. Available at *http://www.coloradotrust.org/sites/default/files/CT_LanguageAccessBrief_final-1.pdf.*

[440] Chen, A.H., Youdelman, M.K., & Brooks, J. (2007). The Legal Framework for Language Access in Healthcare Settings: Title VI and Beyond. *Journal of General Internal Medicine,* 22 Suppl2, 326–327. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2150609.*

[441] Centers for Medicare & Medicaid Services. Guide to Developing a Language Access Plan. 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan-508.pdf.*

[442] CMS Health Services Advisory Group. (2021). CMS Quality Measure Development Plan 2020 Population Health Environmental Scan and Gap Analysis Report for the Quality Payment Program.

[443] Centers for Disease Control and Prevention. (2020). National Diabetes Statistics Report. Available at *https://www.cdc.gov/diabetes/data/statistics-report/index.html.*

[444] Casciato, D.J., Yancovitz, S., Thompson, J., Anderson, S., Bischoff, A., Ayres, S., & Barron, I. (2020). Diabetes-Related Major and Minor Amputation Risk Increased During the COVID–19 Pandemic. *Journal of the American Podiatric Medical Association,* 20–224. Available at *https://doi.org/10.7547/20-224.*

[445] Caruso, P., Longo, M., Signoriello, S., Gicchino, M., Maiorino, M.I., Bellastella, G., Chiodini, P., Giugliano, D., & Esposito, K. (2020). Diabetic Foot Problems During the COVID–19 Pandemic in a Tertiary Care Center: The Emergency Among the Emergencies. *Diabetes Care, 43*(10), e123–e124. Available at *https://doi.org/10.2337/dc20-1347.*

[446] Crocker, R.M., Palmer, K.N.B., Marrero, D.G., & Tan, T.W. (2021). Patient Perspectives on the Physical, Psycho-Social, and Financial Impacts of Diabetic Foot Ulceration and Amputation. *Journal of Diabetes and Its Complications, 35*(8), 107960. Available at *https://doi.org/10.1016/j.jdiacomp.2021.107960.*

[447] Matheson, E.M., Bragg, SW, & Blackwelder, R.S. (2021). Diabetes-Related Foot Infections: Diagnosis and Treatment. *American Family Physician, 104*(4), 386–394.

[448] Suckow, B.D., Newhall, K.A., Bekelis, K., Faerber, A.E., Gottlieb, D.J., Skinner, J.S., Stone, D.H., & Goodney, P.P. (2016). Hemoglobin A1c Testing and Amputation Rates in Black, Hispanic, and White Medicare Patients. *Annals of Vascular Surgery, 36,* 208–217. Available at *https://doi.org/10.1016/j.avsg.2016.03.035.*

[449] Tan, T.W., Shih, C.D., Concha-Moore, K.C., Diri, M.M., Hu, B., Marrero, D., Zhou, W., & Armstrong, D.G. (2019). Disparities in Outcomes of Patients Admitted with Diabetic Foot Infections. *PLoS ONE, 14*(2), e0211481. Available at *https://doi.org/10.1371/journal.pone.0211481.*

[450] Rivero, M., Nader, N.D., Blochle, R., Harris, L.M., Dryjski, M.L., & Dosluoglu, H.H. (2016).

example, evidence has demonstrated that Black patients are less likely to undergo potentially limb-saving interventions, such as revascularization or wound debridement, prior to having an amputation, as compared to White patients.[451] Disparities are also observed by socioeconomic status and region (with rural regions experiencing higher amputation rates).[452] [453]

High-quality care can reduce the risk of amputation, through activities such as regular foot exams to identify ulcers, screening for risk factors such as neuropathy and PAD, patient engagement in foot self-care, therapeutic footwear for patients at high risk of developing ulcers, offloading treatment for patients who develop ulcers, and revascularization to restore blood flow to the limbs.[454]

We are exploring the development of a process quality measure, as well as a composite measure, for inclusion in MIPS, designed to reduce the risk of LEA among patients with diabetes. Based on review of the literature, technical expert panel (TEP) feedback, and prioritization of health equity, we are prioritizing the following process quality measure concept for potential future development: Ulcer Risk Assessment and Follow-Up. The measure would assess the percent of patients with diabetes who receive neurologic and vascular assessments of their lower extremities to determine ulcer risk, have a documented ulcer risk level, and who receive a follow-up plan of care if identified as high risk for ulcer. We intend to consider either adoption and modification of an existing measure or development of a new measure to achieve this measure concept. We are seeking feedback on the following questions in order to understand, account for, and address challenges that may be experienced during development, testing, and implementation of the process measure.

- Are neurological and vascular assessments, and the determination of risk the most important care processes in the prevention of foot ulceration among individuals with diabetes?
- Once a process quality measure concept would be fully developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA? Why or why not?
- Once a process quality measure concept would be fully developed and implemented, would clinicians be able to report performance without undue burden? Why or why not?
- Once a process quality measure concept would be fully developed and implemented, should performance be measured at the clinician level or group level? Is the measure appropriate for all clinicians? If not, to whom should the measure apply?
- What would be the benefits and/or unintended consequences of the process quality measure concept?
- Would a process quality measure concept contribute to health equity? Why or why not?

We may also consider the development of a composite quality measure. A composite measure is a measure that combines two or more individual measures and yields a single score. Composite measures are intended to capture information about complex, multidimensional care processes. Within the context of diabetes and LEA, a composite measure may include individual measures focused on A1C control, cardiovascular risk factors (such as blood pressure control, tobacco non-use), peripheral neuropathy screening, PAD screening, evaluation of footwear, and offloading when ulcers occur. We are seeking feedback on the following questions in order to understand, account for, and address challenges that may be experienced during development, testing, and implementation of a composite quality measure.

- Would the single measures comprising the composite be appropriate? Why or why not?
- Once a composite quality measure concept would be fully developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA?
- Once a process quality measure concept would be fully developed and implemented, should performance be measured at the clinician level or group level? Would the measure be appropriate for all clinicians? If not, to whom should the measure apply?
- Once a quality measure concept would be fully developed and implemented, would clinicians be able to report performance without undue burden? Why or why not?
- What would be the benefits and/or unintended consequences of a composite quality measure concept?
- Would a composite quality measure concept contribute to health equity? Why or why not?

(2) Cost Performance Category

(a) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, 84 FR 62959 through 62979, 85 FR 84877 through 84881, and 86 FR 65445 through 65461, respectively) for a description of the statutory basis for and existing policies pertaining to the cost performance category.

In this rule, we are proposing to update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group.

(b) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and

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Poorer Limb Salvage in African American Men with Chronic Limb Ischemia Is Due to Advanced Clinical Stage and Higher Anatomic Complexity at Presentation. *Journal of Vascular Surgery, 63*(5), 1318–1324. Available at *https://doi.org/10.1016/j.jvs.2015.11.052*.

[451] Rivero, M., Nader, N.D., Blochle, R., Harris, L.M., Dryjski, M.L., & Dosluoglu, H.H. (2016). Poorer Limb Salvage in African American Men with Chronic Limb Ischemia Is Due to Advanced Clinical Stage and Higher Anatomic Complexity at Presentation. *Journal of Vascular Surgery, 63*(5), 1318–1324. Available at *https://doi.org/10.1016/j.jvs.2015.11.052*.

[452] Sutherland, B.L., Pecanac, K., Bartels, C.M., & Brennan, M.B. (2020). Expect delays: Poor Connections Between Rural and Urban Health Systems Challenge Multidisciplinary Care for Rural Americans with Diabetic Foot Ulcers. *Journal of Foot and Ankle Research, 13,* 32. Available at *https://doi.org/10.1186/s13047-020-00395-y*.

[453] Hughes, K., Mota, L., Nunez, M., Sehgal, N., & Ortega, G. (2019). The Effect of Income and Insurance on the Likelihood of Major Leg Amputation. *Journal of Vascular Surgery, 70*(2), 580–587. Available at *https://doi.org/10.1016/j.jvs.2018.11.028*.

[454] Bus, S.A., Lavery, L.A., Monteiro Soares, M., et al. (2020). Guidelines on the Prevention of Foot Ulcers in Persons with Diabetes (IWGDF 2019 update). Diabetes *Metabolism Research and Reviews.* 36(S1):e3269. Available at *https://doi.org/10.1002/dmrr.3269*.

codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties. For more information about past revisions to the operational list, we refer readers to 84 FR 62968 through 62969 and 86 FR 65452 through 65453. The current operational list is available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* Additionally, as required by section 1848(r)(2)(I) of the Act, information on resource use (or cost) measures currently in use in MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of engagement with interested parties, and the percent of expenditures under Medicare Parts A and B that are covered by cost measures must be provided on the website of CMS not later than December 31 of each year.

In prior rulemaking, we have included episode-based measures that focus on specific procedures and conditions in the operational list of care episode and patient condition groups and codes (84 FR 62968 through 62969 and 86 FR 65452 through 65453). Section 1848(r)(2)(D)(ii) of the Act specifies that in establishing the care episode groups, we must take into account the patient's clinical problems at the time items and services are furnished during an episode of care, such as the clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, and the principal procedures or services furnished, as well as other factors we determine appropriate. Section 1848(r)(2)(D)(iii) of the Act specifies that in establishing the patient condition groups, we must take into account the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period, such as 3 months), as well as other factors we determine appropriate. Currently, in the operational list there are 21 care episode groups, which served as the basis for the 15 procedural episode-based measures and the 6 acute inpatient medical episode-based measures that have been established for the cost performance category (83 FR 59767 through 59773, 84 FR 62962 through 62968, and 86 FR 65446 through 65453), and 2 patient condition groups, which served as the basis for the 2 chronic condition episode-based measures that have been established for the cost performance category (86 FR 65446 through 65453). Given that population-based measures, such as the MSPB Clinician and total per capita cost measures, focus on a broader range of patient care, CMS and interested parties have considered them to be distinct from episode-based measures. Therefore, we did not include these two population-based measures in the operational list after they were comprehensively re-evaluated in 2019 and revised for use in MIPS beginning with the CY 2020 performance period/2022 MIPS payment year (84 FR 62974 through 62977). This distinction between episode-based measures and population-based measures also reflects development status as episode-based measures were developed specifically for use in MIPS, while the original versions of the MSPB Clinician and total per capita cost measures were first used in the Value Modifier (VM) program before being adapted for MIPS for the CY 2017 performance period/2019 MIPS payment year (81 FR 77166 through 77168). For additional background on the population-based measures currently in use in MIPS please refer to 84 FR 62969 through 62977.

We propose to add the MSPB Clinician measure to the operational list as a care episode group. Consistent with section 1848(r)(2)(D)(ii) of the Act, the MSPB Clinician measure takes into account the patient's clinical diagnoses at the time of an inpatient hospitalization and includes the costs of various items and services furnished during an episode of care. The MSPB Clinician measure is constructed using many aspects of the same logic as episode-based measures based on the care episode groups currently on the operational list. Both the MSPB Clinician and the episode-based measures are based on clearly-defined episodes and include the services that are clinically related to the clinician's role in the care being assessed. Further, the MSPB Clinician measure attributes episodes under medical Medicare Severity—Diagnosis Related Groups (MS–DRGs) to clinician groups billing at least 30 percent of evaluation and management (E/M) services during an inpatient stay, which is the same attribution logic as the one used for acute inpatient medical episode-based measures. Therefore, designating the MSPB Clinician measure as a care episode group alongside the episode-based measures would ensure that these similarities are reflected in the operational list. For more information on the MSPB Clinician measure, we refer readers to the CY 2020 PFS final rule (84 FR 62974 through 62977) and to the measure specification documents that are available on the QPP Resource Library at *https://qpp.cms.gov/about/resource-library.*

We note that at this time we are not proposing to add the total per capita cost measure to the operational list as a care episode group or patient condition group. The measure is not constructed based on episodes of care; rather, it includes all costs after a primary care-type relationship has been identified. It also does not focus on specific patient conditions as it aims to include all patients where this clinician-patient relationship has been identified. More detailed information on the total per capita cost measure is included in the measure specifications documents available at the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library.*

We do not intend for our proposal to detract from the importance of episode-based measures or affect our plans to continue developing episode-based measures for potential use in MIPS. There are 7 episode-based measures under development and 4 anticipated episode-based measures to begin development this year. The operational list as revised to reflect the proposal is available on the MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.* We seek public comment on our proposal.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886) and the CY 2022 PFS final rule (86 FR 65462 through 65466). We also refer readers to 42 CFR 414.1305 for the definitions of improvement activities and attestation,

§ 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are not proposing any changes to the traditional MIPS improvement activities policies for the CY 2023 performance period/2025 MIPS payment year. However, we are proposing changes to the improvement activities Inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding four new improvement activities; modifying five existing improvement activities; and removing six previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had conducted numerous interviews with highly performing organizations of all sizes and had conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including the patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 71259) and the comments received in response to the MIPS and APMs RFI in relation to the improvement activities performance category, which sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

For the CY 2018 performance period/2020 MIPS payment year, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program CY 2018 performance period/2020 MIPS payment year and future years through subregulatory guidance.[455] In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for the CY 2019 performance period/2021 MIPS payment year and for future years, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the improvement activities Inventory. This process included the requirement to submit a nomination form similar to the one we utilized for CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity, the stakeholder must submit a nomination form (OMB control #0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) Proposed Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix to the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 to the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 to the CY 2020 PFS final rule (84 FR 63514 through 63538), Tables A, B, and C in the Appendix 2 to the CY 2021 PFS final rule (85 FR 85370 through 85377), and Tables A, B, and C in the Appendix 2 to the CY 2022 PFS final rule (86 FR 65969 through 65997) for our previously finalized improvement activities Inventories. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

In this proposed rule, we are proposing to add four new improvement activities, modify five existing improvement activities, and remove six previously adopted improvement activities for the CY 2023 performance period/2025 MIPS payment year and future years. We refer readers to Appendix 2 to this proposed rule for more details.

All of our proposed new improvement activities are responsive to the Administration's goal of advancing health equity for all, as outlined in the President's January 20, 2021, Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (*https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*). Additionally, all of the proposed new improvement activities address Priorities for Reducing Disparities in Health, as described in the CMS Framework for Health Equity (*https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*).

The first proposed new improvement activity, IA_AHE_XX titled ''Use Security Labeling Services Available in Certified Health Information Technology (IT) for Electronic Health Record (EHR) Data to Facilitate Data Segmentation'' would promote the adoption of technology certified to the Security tags—summary of care—send and Security tags—summary of care—receive criteria at 45 CFR 170.315(b)(7) and (b)(8) in the ONC Health IT Certification Program.[456] [457] ONC finalized updated versions of these criteria as part of the ONC 21st Century Cures Act Final Rule (85 FR 25702), which are available for certification by health IT developers. Security tagging allows sharing of certain portions of an EHR while not sharing others, such as sensitive information related to drivers of health. We refer readers to the 2015 Edition final rule (80 FR 62647) for further details. This proposed improvement activity would involve

[455] CMS, *Annual Call for Measures and Activities: Fact Sheet, https://www.cms.gov/Medicare/Quality-IniCtiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf.*

[456] For more information see: *HealthIT.gov.* (2020). *§ .(b)( ) Security tags—summary of care—receive. https://www.healthit.gov/test-method/data-segmentation-privacy-receive#cures_ccg.*

[457] For more information see: *HealthIT.gov.* (2020). *§ .(b)( ) Security tags—summary of care—send. https://www.healthit.gov/test-method/data-segmentation-privacy-send#cures_ccg.*

clinicians working with their EHR vendors to implement technology meeting the security tags criteria in practice systems and clinic workflows. We believe that implementing this technology would improve interoperability while protecting patient privacy, thus improving care delivery and patients' care experience.[458] We believe this activity is likely to improve patient outcomes because protection of patient privacy and increased interoperability helps improve patient care delivery. This proposed improvement activity would address the CMS Framework for Health Equity Priority 1, Expand the Collection, Reporting, and Analysis of Standardized Data.[459]

The proposed new improvement activity IA_AHE_XX titled ''Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients'' supports both CMS Framework for Health Equity Priority 1 and Priority 3, Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities. Eligible clinicians would receive improvement activity credit for creating and implementing a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population, which may include analysis of sexual orientation and gender identity (SO/GI) data to identify and address disparities in care. Actions to implement this activity may include identifying target goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and ONC's United States Core Data for Interoperability [USCDI] as finalized as 45 CFR 170.213), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories. LGBTQ+ individuals face health disparities and challenges navigating and accessing healthcare.[460] [461] We refer readers to the ONC USCDI website at *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi* for further information. Due to lack of clinician training about providing culturally competent and sensitive care for LGBTQ+ individuals, several studies indicate that LGBTQ+ patients, especially gender minority patients, have high rates of negative healthcare experiences.[462] [463] [464] This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on improving care for LGBTQ+ patients. We believe this activity has the potential to improve clinical practice and care delivery because training clinicians about working with LGBTQ+ patients may lead to more positive care experiences and health outcomes.[465]

Another proposed new improvement activity, IA_EPA_XX titled ''Create and Implement a Language Access Plan'' directly responds to the CMS Framework for Health Equity Priority 4, Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services. This activity involves eligible clinicians' creating and implementing a language access plan to address communication barriers for individuals with limited English proficiency. These language access plans should align with standards for communication and language assistance defined in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. We believe that accurate patient-clinician communication, delivered and received in a culturally competent manner, is an essential aspect of improving equity in healthcare and patient outcomes.[466] [467] This proposed improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on language access. We believe this proposed improvement activity has the potential to improve clinical practice and care delivery and is likely to result in improved patient outcomes, because research indicates the importance of accurate clinical communication in achieving positive patient outcomes.[468]

The fourth proposed new improvement activity, IA_ERP_XX titled ''COVID–19 Vaccine Promotion for Practice Staff'' supports CMS Framework for Health Equity Priority 3. COVID–19 vaccination rates in the U.S. can be improved significantly, particularly in underserved communities.[469] Disparities in COVID–19 vaccination rates have been observed specifically among healthcare workers, with physicians and advanced practiced staff being more likely to be vaccinated than nurses and support staff. Also, it has been reported that Black and younger health care workers have lower vaccination rates than other groups of healthcare workers.[470] This proposed improvement activity would fill a gap in

[458] For information about the standards in the certification criteria as well as other standards supporting security tags, see: *HealthIT.gov*. Security tags for sensitive information. *https://www.healthit.gov/isa/security-tags-sensitive-information.*

[459] Centers for Medicare and Medicaid Services. (2022). *CMS framework for health equity. https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity.*

[460] Bosse, J.D., Leblanc, R.G., Jackman, K., & Bjarnadottir, R.I. (2018). Benefits of implementing and improving collection of sexual orientation and gender identity data in electronic health Records. *Computers, Informatics, Nursing, 36*(6), 267–274. *https://doi.org/10.1097/CIN.0000000000000417.*

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[467] Green, A. R., & Nze, C. (2017). Language-based inequity in health care: Who is the ''Poor Historian''? *AMA journal of ethics, 19*(3), 263–271. *https://doi.org/10.1001/journalofethics.2017.19.3.medu1-1703.*

[468] Wasserman, M., Renfrew, M.R., Green, A.R., Lopez, L., Tan-McGrory, A., Brach, C., & Betancourt, J.R. (2014). Identifying and preventing medical errors in patients with limited English proficiency: Key findings and tools for the field. *Journal for Healthcare Quality, 36*(3), 5–16. *https://doi.org/10.1111/jhq.12065.*

[469] Diesel, J., Sterrett, N., Dasgupta, S., Kriss, J.L., Barry, V., Esschert, K.V., Whiteman, A., Cadwell, B.L., Weller, D., Qualters, J.R., Harris, L., Bhatt, A., Williams, C., Fox, L.M., Delman, D.M., Black, C.L., Barbour, K.E., Vanden Esschert, K., & Meaney Delman, D. (2021). COVID–19 vaccination coverage among adults—United States, December 14, 2020–May 22, 2021. *MMWR: Morbidity and Mortality Weekly Report, 70*(25), 922–927. *https://doi.org/10.15585/mmwr.mm7025e1.*

[470] Farah W., Breeher L., Shah V., Hainy C., Tommaso C.P., Swift M.D. Disparities in COVID–19 vaccine uptake among health care workers. Vaccine. 2022 Apr 26;40(19):2749–2754. doi: 10.1016/j.vaccine.2022.03.045. Epub 2022 Mar 25. PMID: 35361500; PMCID: PMC8947975.

the Inventory, which does not currently include an activity focused on COVID–19 vaccination. We believe this activity has the potential to improve clinical practice and is likely to result in improved outcomes and public health, as research indicates the importance of vaccination in reducing the severity and spread of COVID–19.[471]

We are also proposing a number of modifications focused on combining activities where possible and other administrative changes. A particularly important proposed modification to an existing activity is focused on Priority 1 of the CMS Framework for Health Equity, Expand the Collection, Reporting, and Analysis of Standardized Data. We are proposing to: (1) recategorize the IA_CC_14 improvement activity, currently titled ''Practice improvements that engage community resources to support patient health goals,'' from the Care Coordination subcategory to the Achieving Health Equity subcategory, and (2) re-name and re-focus the improvement activity on obtaining and acting on drivers of health data. More specifically, the proposed updated improvement activity with a new ID, IA_AHE_XX, would be titled ''Practice Improvements that Engage Community Resources to Address Drivers of Health.'' We are proposing to modify this improvement activity description to include 'drivers of health' terminology, which better encompasses both 'social determinants of health (SDOH)' and 'health-related social needs (HSRN)' concepts. We are also proposing to update the list of these factors in the description to reflect a more comprehensive array of drivers of health. These proposed modifications build on ongoing efforts to advance health equity in accordance with the Advance Equity Pillar of the CMS Strategic Plan (*https://www.cms.gov/cms-strategic-plan*). We believe the proposed modifications will better enable eligible clinicians to not only improve clinical practice by screening for and addressing drivers of health, but to also receive credit for their efforts. Furthermore, we anticipate such efforts will be associated with improved clinical outcomes because of the potential impact of social drivers of health and other upstream factors on both healthcare and health status.[472] [473] Finally, these proposed modifications would also more clearly align this activity with available evidence and other CMS work in this area, including the CMS Innovation Center's Accountable Health Communities (AHC) Model, designed to test how ''addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs.'' [474]

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category). For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199–77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), and CY 2022 PFS final rule (86 FR 65466–65490).

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2021 PFS final rule at § 414.1320(g)(1) (85 FR 84886) (subsequently re-designated as § 414.1320(h)(1) (86 FR 65671)), for the 2024 MIPS payment year, and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the CY 2025 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2023, up to and including the full CY 2023 (January 1, 2023 through December 31, 2023). We are not proposing any changes to the Promoting Interoperability performance category performance period that we established under § 414.1320(h)(1).

(c) CEHRT Requirements

The Promoting Interoperability Program and the QPP require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition.

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (also referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (also referred to as the 2015 Edition Cures Update) and introduced new 2015 Edition certification criteria. In connection with these updates, ONC also finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. In response to additional calls for flexibility in response to the public health emergency (PHE) for COVID–19, ONC published an interim final rule with comment period on November 4, 2020 entitled, ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule'') (85 FR 70064). In this interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication

[471] Johnson, A.G., Amin, A.B., Ali, A.R., Hoots, B., Cadwell, B.L., Arora, S., Avoundjian, T., Awofeso, A.O., Barnes, J., Bayoumi, N.S., Busen, K., Chang, C., Cima, M., Crockett, M., Cronquist, A., Davidson, S., Davis, E., Delgadillo, J., Dorabawila, V. . . . (2022). COVID–19 incidence and death rates among unvaccinated and fully Vaccinated adults with and without booster doses during periods of delta and omicron variant emergence—25 U.S. jurisdictions, April 4–December 25, 2021. *Morbidity and Mortality Weekly Report (MMWR), 71*(4), 132–138. *https://doi.org/10.15585/mmwr.mm7104e2.*

[472] Raphael, K., Frakt, A., Jha, A., & Glied, S. (2019). *Social and health-systems factors that affect health: What's known and knowable? A review of literature. https://driversofhealth.org/wp-content/uploads/SDH.whitepaper_v8.pdf.*

[473] Gómez, C.A., Kleinman, D.V., Pronk, N., Wrenn Gordon, G.L., Ochiai, E., Blakey, C., Johnson, A., & Brewer, K.H. (2021). Addressing health equity and social determinants of health through healthy people 2030. *Journal of Public Health Management and Practice, 27,* S249–S257. *https://doi.org/10.1097/phh.0000000000001297.*

[474] Accountable Health Communities Model | CMS Innovation Center.

date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023 for 45 CFR 170.315(b)(10), ''electronic health information ((EHI) export'').

In the CY 2021 PFS final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Promoting Interoperability Program or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022 date established in the ONC interim final rule for health IT developers to make updated certified health IT available. After this date, health care providers will be required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023. We are not proposing any changes to this final policy within this proposed rule.

We remind readers that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the EHR reporting period and performance period established for the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected EHR reporting period or performance period of a minimum of any consecutive 90 days in CY 2023, including the final 90 days of 2023 (86 FR 45460 through 45462 and 86 FR 65466, respectively). The eligible hospital, CAH, or MIPS eligible clinician is not required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the EHR reporting period or performance period they have selected.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

i. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

(A) Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 performance period/CY 2023 MIPS payment year. In the CY 2022 PFS final rule (86 FR 65466 through 65467), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2022 performance period/CY 2024 MIPS payment year.

(B) State PDMPs' Progress and Previous Interested Parties' Feedback

In the CY 2020, CY 2021, and CY 2022 PFS final rules (84 FR 62992 through 62994, 85 FR 84887 through 84888 and 86 FR 65467), we described the concerns expressed by interested parties that they believed it was premature for the Promoting Interoperability performance category to require the Query of PDMP measure and score it based on performance. In the CY 2022 PFS proposed rule (86 FR 39410) we discussed our support of efforts to expand the use of PDMPs, describing Federally supported activities aimed at developing a more robust and standardized approach to EHR–PDMP integration, and additional discussions on the feedback we have received from health IT vendors and MIPS eligible clinicians thus far. For more detailed information, we refer readers to the CY 2022 PFS proposed rule (86 FR 39410).

We heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These interested parties stated that EHR developers may face significant cost burdens if they fully develop numerator and denominator calculations and are then required to change the specification at a later date. Interested parties have stated that the costs of additional development would likely be passed on to health care providers without additional benefit, as this development would be solely for the purpose of calculating the measure, rather than furthering the clinical goal of the measure. While we recognize that a numerator/denominator-based measure remains challenging, we also note (as discussed in more detail later in this section) that the widespread availability of PDMPs across the country, and recent progress toward solutions for connecting PDMPs with health care provider EHR systems, has made use of PDMPs feasible through a wide variety of approaches.

(C) Current Status of PDMP Adoption

Today, all 50 States and several localities host PDMPs.[475] The final State to establish a PDMP, the State of Missouri, passed legislation to address this issue in 2021, and is currently working to make its PDMP operational. A 2021 American Medical Association report found that physicians and others used State PDMPs more than 910 million times in 2020.[476] An assessment of PDMPs conducted by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research (IIR) found an increase in the number of PDMPs that are integrated with Health Information Exchanges (HIEs), EHRs, and/or Pharmacy Dispensing Systems (PDSs), with 44 PDMPs integrated in 2021 reflecting an increase from 28 PDMPs with at least one type of integration in 2017. We refer readers to Table 82 for the report's findings on the type of integration and the number of PDMPs that have implemented that type of integration in 2021.

[475] Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

[476] American Medical Association, 2021 Overdose Epidemic Report, *https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf.*

TABLE 82: PDMP Integration – Type and Number of PDMPs*

Type of Integration	# of PDMPs
EHR and PDS	35
HIE and EHR	20
HIE, EHR, and PDS	18
EHR only	5
HIE only	1
PDS only	1

* PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.

Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a free, Federally supported interstate exchange hub for PDMP data. RxCheck is connected to 50 out of 54 PDMPs in states and territories and does not require providers to pay to have the PDMP data integrated into the EHR.

The goal of the project is to allow any health care provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual State PDMPs that are also live on RxCheck. This solution enables health care providers to query PDMPs via existing connections to health information exchange networks. Most States use either RxCheck or Prescription Monitoring Program (PMP) InterConnect or both to facilitate the sharing of PDMP information between States, allowing health care providers to query other States' PDMP information from within their own State PDMP.[477]

We also note that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, has focused on ways to address the nation's opioid epidemic. The SUPPORT for Patients and Communities Act included new requirements for PDMP enhancement and integration, to help reduce opioid misuse and overprescribing and promote the effective prevention and treatment of opioid use disorder beginning in October of 2021. Enhanced Federal matching funds were available to States to support related PDMP design, development, and implementation activities during FYs 2019 and 2020.

(D) Proposed Changes to the Query of PDMP Measure and Related Policies

(aa) Proposal To Change the Query of PDMP Measure Description

The description of the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. In section IV.A.10.c.(4)(d)(i)(D) of this proposed rule, beginning with the performance period in CY 2023, we are proposing to require the Query of PDMP measure for MIPS eligible clinicians participating in the Promoting Interoperability performance category. In section IV.A.10.c.(4)(d)(iii) of this proposed rule, we note that should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we are proposing two exclusions beginning with the performance period in CY 2023: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

Should we finalize the proposals to require the Query of PDMP measure and the associated exclusions, we believe the inclusion of the phrase ''except where prohibited and in accordance with applicable law'' in the description of the Query of PDMP measure and in the language of the exclusion would be duplicative and potentially cause confusion. Therefore, we are proposing to remove the phrase ''except where prohibited in accordance with applicable law'' from the measure description should our proposals to require the Query of PDMP measure and the associated exclusions be finalized. We refer readers to section IV.A.10.c.(4)(d)(i)(D) of this proposed rule for our proposed measure description that would reflect this proposed change and additional proposed policy changes for the Query of PDMP measure.

(ab) Proposal to Require the Query of PDMP Measure

In the CY 2022 PFS final rule (86 FR 65466 through 65467), we noted that the decision to maintain the Query of PDMP as an optional measure for CY 2022 considered the current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act, our ongoing review of alternative measure approaches, and concerns from interested parties about the current readiness across States for implementation of the existing measure. We also noted that this measure can play an important role in helping health care providers to improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions (86 FR 65467); maintaining it as an optional measure with bonus points signals to the clinician and vendor community that this is an important measure which can help spur development and innovation to reduce barriers and challenges (86 FR 65467).

We continue to believe that PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking dispensed controlled substances and improving prescribing practices. Efforts to expand the use of PDMPs and integrate PDMPs with health information technology systems are supported by Federal interested parties including ONC, the Centers for Disease Control and Prevention (CDC),

[477] GAO–21–22, PRESCRIPTION DRUG MONITORING PROGRAMS: Views on Usefulness and Challenges of Programs.

the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Query of PDMP measure offers a way to reward health care providers who participate in current PDMP initiatives, including those supported by Federal partners.

While work continues to improve standardized approaches to PDMP and EHR interoperability, we believe that it is feasible at this time to require MIPS eligible clinicians to report the current Query of PDMP measure, which requires reporting a ''yes/no'' response. Given our policies for the Query of PDMP measure that included increasing the eligible bonus points to reward MIPS eligible clinicians that could report the measure, as well as the recent progress in the availability of PDMPs in all 50 States, and solutions which support accessibility of PDMPs to health care providers, we believe MIPS eligible clinicians have had time to grow familiar with what this measure requires of them, even as technical approaches to the use of PDMPs continue to advance. By requiring a ''yes/no'' response the measure allows MIPS eligible clinicians to use a variety of technical solutions to conduct a query of the PDMP and receive credit for the measure.

Therefore, beginning with the performance period in CY 2023, we are proposing to require MIPS eligible clinicians to report the Query of PDMP measure (which requires reporting a ''yes/no'' response) for the Promoting Interoperability performance category. We would maintain the associated points at 10 points and refer readers to section IV.A.10.c.(4)(l) of this proposed rule for a discussion of our scoring methodology and proposed concurrent changes. As a result of this proposal, the maximum total points available for the Electronic Prescribing Objective would remain at 20 points for CY 2023.We are inviting public comment on these proposals. We are also seeking feedback on ways CMS can ensure coordination and alignment with varying State requirements for PDMPs. Additionally, we invite public comment on what information returned from the PDMP query would be clinically significant.

(ii) Proposed Changes to the Query of PDMP Measure To Include Schedules II, III and IV

The Query of PDMP measure was adopted in the CY 2019 PFS final rule (83 FR 59800 through 59803) as one of two measures under the Electronic Prescribing Objective intended to support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers, and focusing on the advanced use of CEHRT. The measure description for the Query of PDMP measure is as follows: for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law (83 FR 59800 through 59803).

Under the Controlled Substances Act (CSA),[478] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential. We refer readers to Table 83 for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*[479]

[478] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq*.

[479] See also *https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf.*

TABLE 83: Controlled Substance Schedules, Descriptions, and Examples*

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, Demerol, OxyContin, Percocet, morphine, codeine, and amphetamine
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Tylenol with Codeine and anabolic steroids
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Xanax, Klonopin, Valium, and Ativan
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Cough syrups containing codeine

* GAO-21-22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. section 812, and the U.S. Drug Enforcement Administration.

PDMPs are operated at the State level and individual State requirements for reporting and use differ from State to State.[480] Currently, every State collects data on schedules II, III, and IV.[481] Some States collect information about certain non-controlled substances that are potentially subject to abuse or on all prescription drugs.[482] While State laws vary, we note that most State PDMPs require physicians and dispensing pharmacists to review a patient's prescribing information for the past 12 months prior to prescribing or dispensing any Schedule II, III, and IV controlled substances.[483]

PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. We believe that expanding the requirements of the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids would further support HHS initiatives related to the treatment of opioid and substance use disorders by expanding the types of drugs included in the Query of PDMP measure while aligning with the PDMP requirements in a majority of States. We also believe this expansion to include additional Scheduled drugs would facilitate more informed prescribing practices and improve patient outcomes. Therefore, beginning with the performance period in CY 2023, we are proposing to expand the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids.

Proposed Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with policy for the Query of PDMP measure with regard to Schedule II opioids, we are proposing the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug. We also note that this measure would include all permissible prescriptions and dispensing of Schedule II, III, or IV drugs no matter how small the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities. We also note that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date by the same MIPS eligible clinician would not require multiple queries of the PDMP and only one query would have to be performed for this measure. MIPS eligible clinicians would have flexibility to query the PDMP using data from CEHRT in any manner allowed under State law.

We are inviting public comment on these proposals. We are also inviting public comment on whether to expand this measure to include Schedule V or other drugs with potential for abuse.

(iii) Exclusions

In CY 2019 PFS proposed rule, we proposed an exclusion for MIPS eligible clinicians from reporting the Query of PDMP measure beginning with CY 2020 when the measure would have been required by the Promoting Interoperability performance category (83 FR 35922 through 35923). The proposed exclusion was: Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. In the CY 2019 PFS final rule, we finalized the Query of PDMP measure as optional for CY 2019, and thus we did not finalize the proposed exclusion (83 FR 59803). We also stated that we would propose policy for CY 2020 in future rulemaking. To date, we have not adopted any exclusions for this measure because it has remained optional for CY 2020 (84 FR 62992 through 62994), CY

[480] For additional information, we refer readers to *https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605194/;* and *https://www.pdmpassist.org/Policies/Legislative/StatutesAndRegulations.*

[481] *https://www.pdmpassist.org/State.*

[482] GAO report, GAO–21–22 Prescription Drug Monitoring Programs.

[483] *https://www.pdmpassist.org/State.*

2021 (85 FR 84887 through 84888) and CY 2022 (86 FR 65466 through 65467).

In section IV.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule, beginning with the performance period in CY 2023, we are proposing to require MIPS eligible clinicians to report the Query of PDMP measure for the Promoting Interoperability performance category. Should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we believe that an exclusion for the measure would be needed for MIPS eligible clinicians. Therefore, we have revisited the exclusion we proposed in the CY 2019 PFS proposed rule (83 FR 35922 through 35923) and are proposing a modified version here. Specifically, if we finalize our proposal to require the Query of PDMP measure in section IV.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule, we are proposing the following exclusion beginning with the performance period in CY 2023: Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period. In addition, if we finalize our proposal to require the Query of PDMP measure in section IV.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule, we are proposing a second exclusion beginning with the performance period in CY 2023: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. We adopted this same exclusion previously for the e-Prescribing measure (82 FR 53679). We believe this exclusion is also applicable to the Query of PDMP measure based on similar feedback we received from prior rulemaking, where fewer than 100 encounters were supported as an appropriate cutoff number (82 FR 53680). We are also proposing that if a MIPS eligible clinician claims an exclusion for the Query of PDMP measure, we would redistribute the points associated with the Query of PDMP measure to the e-Prescribing measure under the Electronic Prescribing Objective.

We are inviting public comment on these proposals. We are also asking commenters to provide feedback on barriers to reporting on this measure, barriers related to technology solutions, cost, and workflow, that should be considered for MIPS eligible clinicians. We also request comment on any additional exclusions that we should consider proposing for this measure in future rulemaking.

(iv) Future Direction

While we believe that proposing to require the Query of PDMP measure is feasible and appropriate at this time, we are continuing to work with industry and other Federal partners to advance common standards for exchange of information between PDMPs, EHRs, pharmacy information systems, and exchange networks. We believe this work will ultimately allow us to achieve our ideal State, under which we would modify the Query of PDMP measure to be numerator/denominator-based and require use of standardized functionality within certified health IT systems to support the actions associated with the measure and reporting of a numerator and denominator. We will continue to collaborate with ONC to monitor developments across the industry and efforts to advance relevant standards, and plan to revisit this measure in the future to explore further specifying health IT requirements if they become available and are incorporated into the ONC Health IT Certification Program.

Federally supported activities continue to focus on developing and refining standards-based approaches to enable effective integration into clinical workflows; exploring emerging technical solutions to enhance access to and use of PDMP data; and providing technical resources to a variety of interested parties to advance and scale the interoperability of health IT systems and PDMPs. Moreover, updates to certified health IT systems incorporating application programming interfaces (APIs) based on HL7® FHIR® standard version Release 4 (85 FR 25642) can help support future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems. For more information about current and emerging standards related to PDMP data capture and exchange, we refer readers to the ONC Interoperability Standards Advisory.[484]

(e) Health Information Exchange (HIE) Objective: Proposed Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

(i) Background on the Health Information Exchange Objective

The Health Information Exchange (HIE) Objective and its associated measures for MIPS eligible clinicians hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. The Health Information Exchange Objective currently includes three measures: Support Electronic Referral Loops by Sending Health Information; Support Electronic Referral Loops by Receiving and Reconciling Health Information; and Health Information Exchange Bi-Directional Exchange. For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59807 through 59812) and the CY 2021 PFS final rule (85 FR 84888 through 84893).

In the CY 2021 PFS final rule (85 FR 84888 through 84893), we finalized the HIE Bi-Directional Exchange measure, under the Health Information Exchange Objective. The HIE Bi-Directional Exchange measure is worth 40 points, the maximum number of points of the Health Information Exchange Objective, and was finalized as an alternative to reporting on the two existing Health Information Exchange Objective measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. To meet the measure, MIPS eligible clinicians must attest to the following statements:

- Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.
- Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.

We stated that, by enabling bi-directional exchange of information between health care providers and aggregating data across health care providers with disparate systems, HIEs (including a wide range of organizations facilitating health information exchange) can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings (CY 2021 PFS proposed rule, 85 FR

[484] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

50300). We further described how participation in HIEs can amplify health care providers' capacity to share information beyond what a health care provider can achieve through the sending and receiving actions described in the existing measures under the Health Information Exchange Objective, for instance, by facilitating information exchange when a health care provider is unaware of another health care provider's need to receive information about a patient (CY 2021 PFS proposed rule, 85 FR 50300). By finalizing this measure for MIPS eligible clinicians, we sought to ensure that health care providers participating in the Promoting Interoperability performance category would be rewarded for connecting to exchange arrangements that can enable this type of robust information sharing.

(ii) Background on TEFCA

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common Agreement, or TEFCA. ONC's goals for TEFCA are [485]:

- Goal 1: Establish a universal policy and technical floor for nationwide interoperability.
- Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.
- Goal 3: Enable individuals to gather their health care information.

Since we adopted the HIE Bi-Directional Exchange measure, important additional developments have occurred with respect to TEFCA.[486] On January 18, 2022. ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [487] and Common Agreement Version 1.[488] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF)[489] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other—all under commonly agreed-to terms. The Common Agreement is a legal contract that QHINs[490] can sign with the ONC Recognized Coordinating Entity (RCE),[491] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) [492] Providers.[493] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[494] Compared to most nationwide exchange today, the Common Agreement also includes an expanded set of Exchange Purposes [495] beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination—all built upon common technical and policy requirements and to meet key needs of the U.S. health care system. This flexible structure allows interested parties to participate in the way that makes the most sense for them, while also supporting simplified, seamless exchange.

The QTF,[496] which was developed and released by the RCE, describes the

[485] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[486] For more information on current developments related to TEFCA, we refer readers to *www.HealthIT.gov/TEFCA.*

[487] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[488] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022–01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[489] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[490] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[491] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage interested parties to create a roadmap for expanding interoperability over time.

[492] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022–01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[493] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[494] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[495] Exchange Purpose(s): means the reason, as authorized by [the] Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of [the] Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose. *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 *(Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[496] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022),

Continued

functional and technical requirements that a Health Information Network (HIN)[497] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable information exchange modalities, including querying and message delivery across participating entities.

In general, the information to be exchanged within the TEFCA ecosystem allows for the use of Health Level Seven (HL7®) Implementation Guide for Clinical Document Architecture (CDA®) Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 (C–CDA 2.1) document format, including data defined as part of U.S. Core Data for Interoperability (USCDI), with allowance for flexibility to further expand the content to support a multitude of use cases.[498] The Common Agreement and the QTF do not require HL7® Fast Healthcare Interoperability Resource (FHIR®) based exchange. TEFCA allows for the optional exchange of FHIR content using more traditional, established standards to enable the transport of that content. However, TEFCA can nonetheless be a strong catalyst for network enablement of FHIR maturation. To that end, the RCE released a 3-year FHIR Roadmap for TEFCA Exchange, which lays out a deliberate strategy to add FHIR-based exchange under TEFCA in the near future.[499]

(iii) Proposed Enabling Exchange Under TEFCA Measure

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects interested parties across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such interested parties would be: (1) signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [500] under the Common Agreement); (2) in good standing (that is, not suspended) under that agreement; and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient access to more health information. The Common Agreement requires strong privacy and security protections for all entities who elect to participate, including entities not covered by the Health Insurance Portability and Accountability Act (HIPAA).[501]

By connecting to a network that connects to a QHIN or directly to a QHIN, a MIPS eligible clinician can share health information in the same manner as described in the attestation statements previously finalized for the HIE Bi-Directional Exchange measure (CY 2021 PFS final rule (85 FR 84888 through 84893). By connecting to an entity that connects to a QHIN, or connecting directly to a QHIN, that supports sharing information on patients as part of a Framework Agreement,[502] a MIPS eligible clinician would be thereby enabling bi-directional exchange with other health care providers as described in Statement 1 of the HIE Bi-Directional Exchange measure. Since participation in a Framework Agreement as a QHIN, Participant, or Sub-participant will be open to all qualifying entities and will not be restricted by use of a single vendor, a connection via a Framework Agreement would also satisfy the requirements of Statement 2 of the HIE Bi-Directional Exchange measure. Finally, as discussed above, the technical requirements for exchanging information by entities through the Common Agreement and Framework Agreements utilize standards included in certified technology referenced under the CEHRT definition (see 42 CFR 414.1305), including the ability to exchange and receive data using the C–CDA standard (see certification criteria at 45 CFR 170.315(b)(1) and (b)(2)), thus health care providers participating in a Framework Agreement can use the functions of CEHRT to support bi-directional exchange with an HIE.

To offer health care providers more opportunities to earn credit for the Health Information Exchange Objective, and given the alignment between enabling exchange under TEFCA and the existing HIE Bi-Directional Exchange measure, we are proposing to add an additional measure through which a MIPS eligible clinician could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we are proposing to add the following new measure to the Health Information Exchange Objective beginning with the performance period in CY 2023: Enabling Exchange Under TEFCA measure. We propose MIPS eligible clinicians would have three reporting options for the Health Information Exchange Objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable); (2) report on the HIE Bi-Directional Exchange measure; or (3) report on the proposed Enabling Exchange Under TEFCA measure. We propose the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange Objective. Under the current scoring methodology finalized in the CY 2021 PFS final rule, the Health Information Exchange Objective is worth a total of 40 points (85 FR 84894). We note in section IV.A.10.c.(4) of this proposed rule, we are proposing changes to the scoring methodology beginning with the performance period in CY 2023 such that the Health Information Exchange Objective would be worth no more than 30 points. Therefore, under our proposal, the proposed Enabling Exchange Under TEFCA measure would be worth 30 points. We are proposing

https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.

[497] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[498] User's Guide to the Trusted Exchange Framework and Common Agreement—TEFCA (Jan 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-Users-Guide.pdf.*

[499] FHIR® Roadmap for TEFCA Exchange Version 1 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf.*

[500] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[501] Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[502] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

this change to the scoring methodology as a result of our proposal in section IV.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule to make the Query of PDMP measure required and worth 10 points. However, should we not finalize the Query of PDMP measure proposal, we propose the Enabling Exchange Under TEFCA measure would be worth 40 points (the current total point value of the Health Information Exchange Objective). In no case could more than 40 points total be earned for the Health Information Exchange Objective.

We believe the new measure for Enabling Exchange Under TEFCA that we are proposing would incentivize MIPS eligible clinicians to exchange information by connecting directly or indirectly to a QHIN and support health information exchange at a national level. We believe that fulfillment of this measure is an extremely high value action. The overall TEFCA goal of establishing a universal floor of interoperability across the country aligns with our commitment to promoting and prioritizing interoperability and exchange of healthcare data. Incentivizing health care providers to enable exchange under TEFCA is a critical component to advancing healthcare data exchange nationwide. We are proposing a MIPS eligible clinician would report the Enabling Exchange Under TEFCA measure by attestation, and the measure would require a ''yes/no'' response. A ''yes'' response would enable a MIPS eligible clinician to earn the proposed 30 points allotted to the Health Information Exchange Objective. We propose that a MIPS eligible clinician would attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy.
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Similar to the HIE Bi-Directional Exchange measure, to successfully attest to this measure, we propose that a MIPS eligible clinician must use the capabilities of CEHRT to support bi-directional exchange under a Framework Agreement, which includes capabilities that support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the other measures under the Health Information Exchange Objective, which point to the use of CEHRT to support the exchange of the clinical data within the CCDS or the USCDI.

We believe there are numerous certified health IT capabilities that can support bi-directional exchange under a Framework Agreement. For instance, participants may exchange information under a Framework Agreement by using technology certified to the criterion at 45 CFR 170.315(b)(1), ''Care coordination—Transitions of care,'' to transmit C–CDAs across a network. Where supported, participants could also utilize API technology certified to either the criterion at 45 CFR 170.315(g)(8), ''Design and performance—Application access—data category request,'' or (g)(10), ''Design and performance—Standardized API for patient and population services,'' as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable exchange of data in the CCDS or USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information under a Framework Agreement for transitions of care, including modules certified to certification criteria at 45 CFR 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at 45 CFR 170.315(e)(1), ''Patient engagement—View, download, and transmit to 3rd party,'' which supports patient access to their information; and the certification criterion at 45 CFR 170.315(g)(6), ''Design and performance—Consolidated CDA creation performance,'' which supports creation of a summary of care record. We recognize that entities that will connect directly or indirectly to a QHIN are currently interacting with health care providers using certified health IT in a variety of ways, and, as with the Bi-Directional HIE Exchange measure, believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data under a Framework Agreement.

The Enabling Exchange Under TEFCA measure could offer health care providers an alternative to earn credit for the Health Information Exchange Objective. The Enabling Exchange Under TEFCA measure would not require a MIPS eligible clinician to assess whether they participate in a health information exchange that meets the attributes of attestation Statement 2 under the HIE Bi-Directional Exchange measure regarding exchange across a broad network of unaffiliated exchange partners including those using disparate EHRs. These attributes are key to the goals of TEFCA, which aims to offer health care providers a uniform set of expectations around information sharing regardless of which network for information exchange they participate in.

We are inviting public comment on these proposals. As noted in section IV.A.5. of this proposed rule, we are also requesting comment on other ways that TEFCA can advance CMS policy and program objectives, including how TEFCA can support exchange of information required under other measures in the Promoting Interoperability performance category. For instance, how can TEFCA support exchange of information specified under the Public Health and Clinical Data Exchange and the Patient Access to their Health Information objectives?

(f) Modifications to the Public Health and Clinical Data Exchange Objective

(i) Background

The Promoting Interoperability performance category for MIPS eligible clinicians has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange Objective. Effective responses to public health events, such as the COVID–19 PHE, require fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). Health care providers collect these data for patient care, and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

There are five measures under the Public Health and Clinical Data Exchange Objective: Immunization Registry Reporting; Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59795, 59815 through 59817). In the CY 2022 PFS final rule (86 FR 65469 through 65475), we

finalized the requirement for MIPS eligible clinicians to report two of the five measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022: Immunization Registry Reporting; and Electronic Case Reporting. These two measures will put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening two important public health functions: (1) case surveillance; and (2) vaccine uptake. Requiring these measures will enable nationwide automated case reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies. (See *https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html https://www.healthit.gov/topic/safety/safer-guides.*)

(ii) Proposed Revisions to Active Engagement

(A) Background

The Promoting Interoperability performance category has been an important mechanism for encouraging data exchange between health care providers and public health agencies through the Public Health and Clinical Data Exchange Objective. We believe requiring MIPS eligible clinicians to report on the Immunization Registry Reporting measure and Electronic Case Reporting measure will motivate EHR vendors to implement the necessary capabilities in their products and encourage MIPS eligible clinicians to engage in the reporting activities described in the measures.

Despite these gains, ensuring the nation's thousands of clinicians implement and initiate data production for these vital public health capabilities remains an ongoing and important effort. The Promoting Interoperability performance category provides an opportunity to continue strengthening the incentives for MIPS eligible clinicians to engage in these essential reporting activities. Without adequate incentives, it will be difficult to attain the comprehensive data exchange needed to ensure fast, complete, actionable data in response to future public health threats.

In the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864), beginning with the EHR reporting period in 2016, we established a definition for active engagement under the Public Health and Clinical Data Registry Reporting Objective (subsequently renamed for MIPS the Public Health and Clinical Data Exchange Objective, see 83 FR 59815 through 59817). Active engagement is defined as when an eligible professional (now a MIPS eligible clinician) is in the process of moving towards sending ''production data'' to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term ''production data'' refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers. We established the following three options for eligible professionals to demonstrate active engagement:

- *Option 1—Completed registration to submit data:* The eligible professional registered to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the eligible professional is awaiting an invitation from the PHA or CDR to begin testing and validation. Eligible professionals that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.
- *Option 2—Testing and validation:* The eligible professional is in the process of testing and validation of the electronic submission of data. The eligible professional must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in the eligible professional not meeting the measure.
- *Option 3—Production:* The eligible professional has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

For more information about the current options for active engagement, we refer readers to the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864).

(B) Proposed Revision to Options for Active Engagement

The three active engagement options provided flexibility for eligible professionals and MIPS eligible clinicians to meet the measures under the Public Health and Clinical Data Registry Reporting Objective/Public Health and Clinical Data Exchange Objective in a variety of ways, but they did not provide an incentive to move through the options and get to option 3, production, where there is the ongoing electronic submission of data. Option 1, completed registration to submit data, was an important option in 2016 as many PHAs and CDRs were starting to come online, and thus the provision of this option recognized that many eligible professionals were just beginning to engage in electronic data exchange with PHAs and CDRs. Now many years have passed, and we believe that MIPS eligible clinicians have had ample time to complete option 1.

Thus, we propose to consolidate current options 1 and 2 into one option beginning with the performance period in CY 2023, as follows:

- Proposed Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation). The MIPS eligible clinician must first register to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted. Registration must be completed within 60 days after the start of the EHR reporting period, while awaiting an invitation from the PHA or CDR to begin testing and validation. MIPS eligible clinicians that have registered in previous years do not need to submit an additional registration for subsequent performance periods. Upon completion of the initial registration, the MIPS eligible clinician must begin the process of testing and validation of the electronic submission of data. The MIPS eligible clinician must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within a performance period would result in the MIPS eligible clinician not meeting the measure.

Eligible clinicians could select this option if they have previously completed the initial registration (existing Option 1). They could also select this option if they are currently in the process of testing and validation (existing Option 2).

- Proposed Option 2. Validated Data Production (current option 3, production). The MIPS eligible clinician has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

Under this proposal, a MIPS eligible clinician must demonstrate their level of active engagement at either proposed Option 1 (pre-production and validation) or proposed Option 2 (validated data production) to fulfill each measure. We are inviting public comment on these proposed changes to the options for active engagement.

(C) Proposed Reporting Requirement for Level of Engagement

MIPS eligible clinicians currently are not required to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange Objective. We believe that this information would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding MIPS eligible clinicians and moving them to the Validated Data Production phase. During the recent COVID–19 PHE, we recognized the importance of public health reporting (as discussed further in section IV.A.10.c.(4)(f)(i) of this proposed rule), and we believe that knowing the level of active engagement that a MIPS eligible clinician selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage. Our goal is for all health care providers nationwide to be at the Validated Data Production stage so that data will be actively flowing and public health threats can be monitored. Therefore, for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures a MIPS eligible clinician chooses to report, we propose to require MIPS eligible clinicians to submit their level of active engagement, either Pre-production and Validation or Validated Data Production (as proposed in section IV.A.10.c.(4)(B)), for each measure they report beginning with the performance period in CY 2023. If our proposal to reduce the three current options of active engagement to two options is not finalized, we propose to require MIPS eligible clinicians to submit one of the three current options of active engagement for each measure they report.

We are inviting public comment on this proposed change to require submission of the level of active engagement.

(D) Proposed Changes to the Duration of Active Engagement Options

MIPS eligible clinicians currently are not required to advance from one option of active engagement to the next within a certain period of time. Beginning with the performance period in CY 2023, we are proposing that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level in the next performance period for which they report a particular measure. For example, under this proposal, if a MIPS eligible clinician submits the Immunization Registry Reporting measure for the performance period in CY 2023 at the level of active engagement for proposed option 1 (Pre-production and Validation), the clinician must submit the Immunization Registry Reporting measure at the level of active engagement for proposed option 2 (Validated Data Production phase) for the next performance period in CY 2024, or they would fail to satisfy the Public Health and Clinical Data Exchange Objective. To use an optional measure as an example to illustrate this proposal, if a MIPS eligible clinician chooses to submit the Syndromic Surveillance Reporting measure for the performance period in CY 2023 at the level of active engagement for proposed option 1 (Pre-production and Validation) and then chooses to submit the Syndromic Surveillance Reporting measure for a later performance period, the clinician would have to submit the measure at the level of active engagement for proposed option 2 (Validated Data Production phase) for the next performance period for which they choose to submit the measure. The options for active engagement assume the same PHA or CDR is used by the MIPS eligible clinician. In the event a MIPS eligible clinician chooses to switch between one or more CDRs or PHAs, we are proposing they would be permitted to spend one additional performance period at the Pre-production and Validation phase to assist with onboarding to the new CDR or PHA. As electronic transmission of high-quality data is achieved at the Validated Data Production phase, we want all MIPS eligible clinicians to reach this level.

We are inviting public comments on this proposed change to the duration of the active engagement options.

(E) Public Health Reporting and Information Blocking

The ONC 21st Century Cures Act final rule (85 FR 25642) implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. The 21st Century Cures Act final rule established a regulatory definition of information blocking, under which information blocking is, in general, a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider (actors [503]) that, except as required by law or covered by an exception in 45 CFR part 171, subparts B or C, is likely to interfere with (as defined in 45 CFR 171.102) access, exchange, or use of EHI.[504] [505] For a health care provider (as defined in 45 CFR 171.102), information blocking (see 45 CFR 171.103) means a practice (except as required by law or covered by an exception defined in 45 CFR part 171) that is likely to interfere with access, exchange, or use of EHI that the health care provider knows is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.[506] [507]

ONC recently released an information blocking frequently asked question (FAQ) (IB.FAQ43.1.2022FEB) that highlights important points about public health reporting and information blocking.[508] Specifically, if an actor is required to comply with another law that relates to the access, exchange, or use of EHI, failure to comply with that law may implicate the information blocking regulations. As an example, where a law requires actors to submit EHI to public health authorities, an actor's failure to submit EHI to public health authorities could be considered an interference under the information blocking regulations. For example, many States legally require reporting of certain diseases and conditions to detect

[503] Actor is defined in 45 CFR 171.102 as ''health care provider, health IT developer of certified health IT, health information network or health information exchange.''

[504] For purposes of the definition of information blocking, for the period before October 6, 2022, electronic health information is defined in 45 CFR 171.103(b). As of that date, electronic health information will be defined as it is in 45 CFR 171.102.

[505] In order for a practice to be considered information blocking, additional requirements at 45 CFR 171.103(a)(2) or (a)(3) apply, depending on the type of actor engaging in the practice.

[506] For other types of actors (health IT developers of certified health IT and health information networks or health information exchanges, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

[507] The exceptions to the definition of information blocking (practices that are required by law or covered by an exception in 45 CFR part 171, subparts B or C) described in the previous sentence apply to this definition as well.

[508] See *https://www.healthit.gov/curesrule/faq/would-not-complying-another-law-implicate-information-blocking-regulations.*

outbreaks and reduce the spread of disease. Should an actor that is required to comply with such a law fail to report,the failure could be an interference with access, exchange, or use of EHI under the information blocking regulations. Practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking, consistent with additional ONC frequently asked questions.[509]

(g) Proposed Changes to the Scoring Methodology for the Performance Period in CY 2023

For ease of reference, Table 84 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2023 performance period/CY 2025 MIPS payment year as revised to reflect the proposals made in this proposed rule.

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[509] See *https://www.healthit.gov/curesrule/faq/how-would-any-claim-or-report-information-blocking-be-evaluated.*

TABLE 84: Objectives and Measures for the Promoting Interoperability Performance Category for the Performance Period in CY 2023

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history*.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. writes fewer than 100 permissible prescriptions during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health	Number of electronic summary of care records in the denominator for	Number of electronic summary of care records received using CEHRT for	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which

Objective	Measure	Numerator	Denominator	Exclusion
	Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA* MIPS eligible clinicians would attest to the following: • Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. • Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case

Objective	Measure	Numerator	Denominator	Exclusion
				reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period: OR 4. for the CY 2022 performance period/CY 2024 MIPS payment year only, the MIPS eligible clinician uses CEHRT that is not certified to the electronic case reporting certification criterion at § 170.315(f)(5) prior to the start of the performance period they select in CY 2022.
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical,	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
administrative, and physical safeguards.	encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

* Signifies a proposal made in this CY 2023 PFS proposed rule.

In this proposed rule, we are making various proposals that would affect the scoring of the objectives and measures for the performance period in CY 2023. For reference, Table 85 reflects the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2022.

TABLE 85: Scoring Methodology for the Performance Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)
Health Information Exchange -OR-	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 2 measures: • Immunization Registry Reporting • Electronic Case Reporting	10 points
	Report on any one of the following measures: • Public Health Registry Reporting OR • Clinical Data Registry Reporting OR • Syndromic Surveillance Reporting	5 points (bonus)

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored. In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review and actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

In proposing to make the Query of PDMP measure required, we would retain the 10 points associated with it, which are allocated as bonus points for the performance period in CY 2022. To accommodate this change if our proposal is finalized, we are proposing to reduce the points associated with the Health Information Exchange Objective measures from the current 40 points to 30 points beginning with the CY 2023 performance period.

The Public Health and Clinical Data Exchange Objective, with its two required measures, is currently worth only 10 points. Despite requiring certain measures to make the objective more effective in promoting public health data electronic exchange, the total number of points did not change between CY 2021 and CY 2022. We believe that increasing the point value of the Public Health and Clinical Data Exchange Objective would create a more meaningful incentive for MIPS eligible clinicians to engage in the electronic reporting of public health information and recognize the importance of public health systems affirmed by the COVID–19 pandemic. Increasing the point value would make the Public Health and Clinical Data Exchange Objective a more central piece of the Promoting Interoperability performance category and better incentivize MIPS eligible clinicians to implement these essential public health data exchange capabilities. Without adequate incentives, there remains a risk that MIPS eligible clinicians will simply not prioritize implementing these capabilities, which are essential to ongoing efforts to address COVID–19 and will be indispensable for responding to future public health threats and emergencies. Increasing the point value would more appropriately incentivize MIPS eligible clinicians to engage in the electronic reporting of public health information and would align the value of the objective with the objective's importance and the effort necessary to meet the required measures.

Thus, we are proposing to increase the points allocated to the Public Health and Clinical Data Exchange Objective from 10 to 25 points to better align with the true value of this objective beginning with the CY 2023 performance period. We believe assigning 25 points to the objective reflects the importance of comprehensive, nationwide health care data exchange between MIPS eligible clinicians and public health agencies. Nationwide health care data exchange would provide immense value to the public by improving the speed and effectiveness of public health responses, as well as to MIPS eligible clinicians, since better public health response reduces pressure on clinicians, which can be overwhelmed in a public health crisis. To balance the increase in the points associated with the Public Health and Clinical Data Exchange Objective, we are proposing to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25 points beginning with the CY 2023 performance period. We are proposing to revise the regulatory text for scoring the Promoting Interoperability performance category at § 414.1380(b)(4)(ii)(B) and (C) to reflect these proposals for scoring the objectives and measures. We are inviting public comment on these proposed changes to our scoring methodology.

Table 86 reflects the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2023 if the proposals discussed are finalized.

TABLE 86: Scoring Methodology for the Performance Period in CY 2023

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP*	10 points*	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points*	
	-OR-		
	Enabling Exchange under TEFCA*	30 points*	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required
Public Health and Clinical Data Exchange	Report the following two measures*: • Immunization Registry Reporting • Electronic Case Reporting	25 points*	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)*	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review and actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).
*Signifies a proposal made in this CY 2023 PFS proposed rule.

The maximum points available in Table 86 do not include the points that would be redistributed in the event an exclusion is claimed. For ease of reference, Table 87 shows how points would be redistributed among the objectives and measures for the performance period in CY 2023 in the event a MIPS eligible clinician claims an exclusion, if the proposals discussed in this section are finalized.

TABLE 87: Exclusion Redistribution for Performance Period in CY 2023

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE Objective
	Query of PDMP*	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA*	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following five measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review and actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).
*Signifies a proposal made in this CY 2023 PFS proposed rule.

For ease of reference, Table 88 lists the objectives and measures for the Promoting Interoperability performance category for the performance period in CY 2023 and the 2015 Edition certification criteria.

TABLE 88: Promoting Interoperability Performance Category Objectives and Measures and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition (CY 2022 EHR Reporting Period)
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance

Objective	Measure	2015 Edition (CY 2022 EHR Reporting Period)
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria, revising and removing existing criteria (85 FR 25667 through 25668). These changes are required beginning with the CY 2023 performance period.

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(h) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) for the performance periods in CY 2017 through 2022 (CY 2019 through CY 2024 MIPS payment years) under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category and discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the 2018 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, we initially found approximately 34 percent submitted data individually for the Promoting Interoperability performance category. However, after further review and the refinement of our analytics, we found that this percentage was 24 percent, not 34 percent. For the 2019 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 30 percent submitted data individually for the Promoting Interoperability performance category, a modest increase from 2018. For the 2020 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 27.5 percent submitted data individually for the Promoting Interoperability performance category, a modest decrease from 2019. For the 2021 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually for MIPS, approximately 21.3 percent submitted data individually for the Promoting Interoperability performance category, a decrease from 2020.

Due to the continued relatively low numbers of NPs, PAs, CRNAs, or CNSs that submitted data individually for the Promoting Interoperability performance category for prior performance periods, we did consider proposing to extend the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) for another year (for the CY 2023 performance period/2025 MIPS payment year). However, we believe that incentivizing more of these types of MIPS eligible clinicians to adopt and use CEHRT and submit data for the Promoting Interoperability performance category is important for increased interoperability and data exchange nationwide. We adopted the reweighting policy beginning with the first year of MIPS (the CY 2017 performance period/2019 MIPS payment year), and we believe that there has been sufficient time for NPs, PAs, CRNAs, and CNSs to adopt and implement CEHRT. At this point in the program's maturity, we are concerned that the reweighting policy itself might be serving as a disincentive to these types of MIPS eligible clinicians adopting and using CEHRT, which would be an unintended consequence. We believe it is possible that these clinician types are now able to submit data individually on the measures for the Promoting Interoperability performance category, but they are

choosing not to because they would prefer for the performance category to be reweighted and not to contribute to their final score. Further, we believe that there are sufficient measures applicable and available in the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs. The measures that may not apply to these clinician types, such as the e-Prescribing measure, have exclusions that can be claimed if applicable. We considered the impact that not extending the policy may have on MIPS eligible clinicians in small practices, but we believe that the policy we established in the CY 2022 PFS final rule at § 414.1380(c)(2)(i)(A)(*4*)(*ii*)) to automatically assign a weight of zero to the Promoting Interoperability performance category for MIPS eligible clinicians in a small practice will result in very few NPs, PAs, CRNAs, and CNSs being affected. Further, we remind readers that a MIPS eligible clinician who meets the criteria for a significant hardship may submit an application to reweight the Promoting Interoperability performance category based on a significant hardship, such as lack of control over the availability CEHRT and insufficient internet access (81 FR 77240 through 77243, 82 FR 53680 through 53686, 82 FR 53783 through 53785, and 85 FR 84984).

For these reasons, we are not proposing to continue the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score for NPs, PAs, CRNAs, or CNSs for the CY 2023 performance period/2025 MIPS payment year. We are, however, requesting public comment on whether we should continue this policy for the CY 2023 performance period/CY 2025 MIPS payment year, and we may decide to take a different approach in the final rule depending on the comments we receive. We are particularly interested in comments on potential barriers to CEHRT adoption and implementation that may impact one or more of these clinician types, as well as comments on the applicability of the Promoting Interoperability performance category measures to NPs, PAs, CRNAs, or CNSs.

(ii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2019 PFS final rule (83 FR 59819 through 59820), we established that we will apply the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are non-physician practitioners (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the CY 2019 performance period. The reweighting policy for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals is codified at § 414.1380(c)(2)(i)(A)(*4*)(*i*).We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. We extended this policy for the performance periods in CY 2020 (84 FR 63003 through 63004), CY 2021 (85 FR 84895), and CY 2022 (86 FR 65488 through 65489). We analyzed the data from the CY 2019 performance period/CY 2021 MIPS payment year, and approximately 18.4 percent of occupational therapists, 2 percent of physical therapists, and 1 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, approximately 18.8 percent of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category. We analyzed the data from the CY 2020 performance period/CY 2022 MIPS payment year, and approximately 3.3 percent of occupational therapists, 1.4 percent of physical therapists, and 0.6 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, 0 percent (rounded from 16 total clinicians) of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category. We analyzed the data from the CY 2021 performance period/CY 2023 MIPS payment year, and 0 percent of occupational therapists, 0.3 percent of physical therapists, 0.5 percent of clinical psychologists who submitted data individually for MIPS, submitted data individually for the Promoting Interoperability performance category. For qualified speech-language pathologists, qualified audiologists, and registered dieticians/nutrition professionals, 6.7 (6.66) percent of those who submitted data individually for MIPS also submitted data individually for the Promoting Interoperability performance category.

Based on low participation, it is possible that these clinician types may be finding that there are not sufficient measures that are applicable to them. As with NPs, PAs, CRNAs, and CNSs, however, it is also possible that the reweighting policy itself might be serving as a disincentive to these types of MIPS eligible clinicians adopting and using CEHRT, and that they are choosing not to submit data individually on the measures because they would prefer for the performance category to be reweighted and not to contribute to their final score. Because these clinician types were added to the definition of a MIPS eligible clinician under § 414.1305 more recently than NPs, PAs, CRNAs, and CNSs, we believe it would be appropriate to continue the existing reweighting policy for them for one more year. Therefore, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals only for the CY 2023 performance period/2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)*(4)(i)* to reflect the proposal. We want to continue to encourage these types of MIPS eligible clinicians to adopt and use CEHRT, which would contribute to increased interoperability and data exchange nationwide; therefore, we do not anticipate proposing in future rulemaking to extend the policy for additional years.

We invite comments on this proposal.

(iii) Clinical Social Workers

In the CY 2022 PFS final rule (86 FR 65387 through 65389), we added clinical social workers to the definition of a MIPS eligible clinician under § 414.1305, beginning with the CY 2022 performance period/CY 2024 MIPS payment year. This clinician type was not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive

reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers also were not eligible for Medicaid EHR incentive payments. We stated that clinical social workers may lack experience with the adoption or use of CEHRT, and that we believed there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to them (86 FR 65489). For the CY 2022 performance period/CY 2024 MIPS payment year, we established that we will apply to clinical social workers the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians who are non-physician practitioners (86 FR 65489). The reweighting policy for clinical social workers is codified at § 414.1380(c)(2)(i)(A)(*4)(iii).*

CY 2022 is the first year that clinical social workers are considered MIPS eligible clinicians, and thus we do not yet have any performance period data that we could use to evaluate whether the Promoting Interoperability performance category measures are applicable and available to this type of MIPS eligible clinician. We are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/CY 2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)(*4)(iii*) to reflect the proposal. We will evaluate whether the policy should be continued for future years when we have performance period data available.

(i) Patient Access to Health Information Measure—Request for Information (RFI)

Patient use of portals to access their health information has been tied to benefits such as improvements in access, quality of care, and health outcomes, and reductions in healthcare expenditures.[510] In particular, access to health information has been shown to enable the discovery of medical errors, to improve medication adherence, and to promote communication between the patient and health care provider.[511] Health care provider encouragement (and other facilitating conditions), perceived usefulness, ease of use, control of health information, and enhanced communication are demonstrated as facilitators, while concerns of privacy, security, and lack of awareness have been tied to barriers of use.[512] [513]

The Health Information National Trends Survey (HINTS), a large, nationally representative survey operated by the National Cancer Institute (with support from ONC), is conducted routinely and contains key utilization data on consumer access and use of their online medical record through patient portals. The HINTS results showed the rates of individuals being offered and subsequently using their health information through a patient portal, as well as use of mobile health applications (apps) and the role health care providers play in encouraging use.[514] Results showed that health care providers and staff have a substantial role in influencing patient use of the portal.

In the past for the Promoting Interoperability performance category, we attempted to promote patient access to their health information through measuring the number of patients who actively engaged with the electronic health record through the View, Download, Transmit (VDT) measure in the CY 2017 Quality Payment Program final rule (81 FR 77228 through 77237). In the CY 2019 PFS final rule (83 FR 59812 through 59814), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective and updated the measures within the Provider to Patient Exchange Objective. Specifically, we removed the standalone VDT measure from the Promoting Interoperability performance category in response to feedback from interested parties, including physician specialty societies ongoing concern with measures that require patient action for successful submission (83 FR 59814). We have also noted that data analysis of VDT measure supports concerns from interested parties that barriers exist which impact a clinician's ability to meet them. Interested parties have indicated that success of the measure is reliant upon the patient, who may face barriers to access which are outside a clinician's control. Additionally, in the CY 2019 PFS final rule (83 FR 59812 through 59813), we changed the name of the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information and finalized changes to the measure description. These measure changes included a requirement for MIPS eligible clinicians to provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice (83 FR 59812 through 59813). This change emphasized timely electronic access of patient health information rather than requiring health care providers to be accountable for patient actions.

Through the current Provide Patients Electronic Access to Their Health Information measure in the Provider to Patient Exchange Objective, we are ensuring that patients have access to their health information through any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the CEHRT of the MIPS eligible clinician. Promoting the use of API-enabled applications that provide timely access to updated information whenever the patient needs that information is an integral step in enhancing patient access and use of their health information. These API-enabled applications should be configured using standardized technology and contain the information the patient needs to make informed decisions about their care in a way the patient understands, and that recognizes the community's level of access to devices and internet connectivity. While we removed the VDT measure holding MIPS eligible clinicians responsible for patient action (83 FR 59814), we still require that the technical capabilities be in place within a MIPS eligible clinician's CEHRT through the Provide Patients Electronic Access to Their Health Information measure should patients choose to access and use their health information (83 FR 59812 through 59813).

We continue to believe in the importance of taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their electronic health information and can be assured that their health information will follow them as they move throughout the health care system. Recognizing the concerns and barriers

[510] Ronda MC, Dijkhorst-Oei LT, Rutten GE. Reasons and barriers for using a patient portal: survey among patients with diabetes mellitus. J Med Internet Res. 2014 Nov 25;16(11):e263. doi: 10.2196/jmir.3457. PMID: 25424228; PMCID: PMC4260081.

[511] Wildenbos GA, Peute L, Jaspers M. Facilitators and Barriers of Electronic Health Record Patient Portal Adoption by Older Adults: A Literature Study. Stud Health Technol Inform. 2017;235:308–312. PMID: 28423804.

[512] Powell KR. Patient-Perceived Facilitators of and Barriers to Electronic Portal Use: A Systematic Review. Comput Inform Nurs. 2017 Nov;35(11):565–573. doi: 10.1097/CIN.0000000000000377. PMID: 28723832.

[513] Alaa A. Abd-alrazaq, Bridgette M. Bewick, Tracey Farragher, Peter Gardner, Factors that affect the use of electronic personal health records among patients: A systematic review, International Journal of Medical Informatics, Volume 126, 2019, Pages 164–175, ISSN 1386–5056, *https://doi.org/10.1016/j.ijmedinf.2019.03.014.*

[514] Johnson C, Richwine C, Patel V. Office of the National Coordinator for Health Information Technology (ONC) Data Brief, No. 57 (September 2021). Individuals' Access and Use of Patient Portals and Smartphone Health Apps, 2020.

with the previous VDT measure discussed previously, but acknowledging the advancements made within the health IT industry over the past few years, this request for information is seeking a broad array of public comments regarding how to further promote equitable patient access and use of their health information without adding unnecessary burden on the MIPS eligible clinician or group. Specifically, we are seeking public comment on the following questions:

• Moving beyond providing the information and technical capabilities to access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?

++ Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access?

++ Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?

++ Are there certain tools found to be useful in promoting patient access and use of their health information?

• Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care.[515] [516]

++ What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?

• Additional analysis of HINTS data provides insights into common barriers to patient portal access and use as well as characteristics that can help predict which individuals are more likely to experience certain barriers (for example, preference for in-person communication with their health care provider is one of the most prevalent barriers experienced more often by older adults and women).[517]

++ What are the most common barriers to patient access and use of their health information that have been observed? Are there differences by populations or individual characteristics? For example, are there barriers caused by lack of accessibility to patients due to disability or limited English proficiency?

• Patients' health information may be found in multiple patient portals. How could CMS or HHS facilitate individuals' ability to access all their health information in one place?

++ If patient portals connected to a network participating in the recently launched TEFCA,[518] [519] would this enable more seamless access to individual health information across various patient portals?

• With the advancement of HIT, EHRs and other health-related communication technologies, there are concerns that implementation of these technologies can lead to unintended consequences that exacerbate existing health disparities within populations who could receive greater benefits but are less likely to adopt them.[520] [521] [522] [523] What policy, governance and implementation strategies or other considerations are necessary to ensure equal access to consumer-facing health technologies including patient portals and mobile health applications, as well as equitable implementation and appropriate design and encouragement of use across all populations?

• What challenges do MIPS eligible clinicians face when addressing patient questions and requests resulting from patient access of patient portals or access of data through use of a mobile app? What can be done to mitigate potential burden?

• For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?

• Do you believe the API and app ecosystem are at the point where it would be beneficial to revisit adding a measure of patient access to their health information which assesses clinicians on the degree to which their patients actively access their health information? What should be considered when designing a measure of patient access of their health information through portals or apps?

We welcome input on how we can encourage and enable patient access to and use of their health information to manage and improve their care across the care continuum.

(5) APM Entity Level Participation for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

In the CY 2021 PFS final rule (85 FR 84896), we finalized our policy to terminate the APM scoring standard effective January 1, 2021, and to retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the CY 2021 MIPS performance period. Therefore, we redesignated, in part, the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and titled that section ''APM Entity Groups.''

(b) APM Entity Level Reporting of Promoting Interoperability Performance Category

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to allow APM Entities to report to traditional MIPS using any available MIPS reporting pathway, including the APM Performance Pathway (APP), traditional MIPS and, in the future, MIPS Value Pathways (MVPs).

We finalized that APM Entities that do not report through the APP will continue to have the cost performance category reweighted to zero percent of their MIPS final score, but will be required to report and be scored on the three remaining MIPS performance categories, including quality, IA, and promoting interoperability. We explained in that rule that the PI performance category would continue to be scored for multi-TIN APM Entities using the promoting interoperability roll-up calculation described at § 414.1317(b)(1) (85 FR 84897).

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[515] Sun M, Oliwa T, Peek ME, Tung EL. Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record. Health Affairs 41, No. 2 (2022): 203–211. doi:10.1377/hlthaff.2021.01423.

[516] Himmelstein G, Bates D, Zhou L. Examination of Stigmatizing Language in the Electronic Health Record. JAMA Netw Open. 2022;5(1):e2144967. doi:10.1001/jamanetworkopen.2021.44967.

[517] Turner K, Clary A, Hong Y, Alishahi Tabriz A, Shea CM. Patient Portal Barriers and Group Differences: Cross-Sectional National Survey Study. J Med Internet Res 2020;22(9):e18870.

[518] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange. ONC January 2022: *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[519] Common Agreement for Nationwide Health Information Interoperability V1. ONC. January 2022: *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[520] Craig S, McPeak KE, Madu C, Dalembert G. Health information technology and equity: Applying history's lessons to tomorrow's innovations. Current Problems in Pediatric and Adolescent Health Care. Volume 52, Issue 1, 2022.

[521] Antonio MG, Petrovskaya O, Lau F. Is research on patient portals attuned to health equity? A scoping review. JAMIA, 26(8–9), 2019, 871–883.

[522] Sarkar U, Karter AJ, Liu JY, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the diabetes study of Northern California (DISTANCE). J Health Commun 2010; 15 (Suppl 2): 183–96.

[523] Ackerman SL, Sarkar U, Tieu L, et al. Meaningful use in the safety net: a rapid ethnography of patient portal implementation at five community health centers in California. J Am Med Inform Assoc 2017; 24 (5): 903–12.

It has come to our attention through feedback from interested parties that many of the workstream modifications, as well as data aggregation and integration tools that are likely to be used by multi-TIN APM Entities, such as use of the FHIR API or hiring vendors to complete the more complex reporting activities required for reporting APM Entity level eCQMs could also be used to collect data and submit for the promoting interoperability performance category at the APM Entity level.

It is also our understanding that it is possible that an APM Entity may represent only a single practice site or specialty within a larger multi-specialty TIN. We believe that in these circumstances the APM Entity may have both the ability and desire to report on the promoting interoperability performance category at the APM Entity level, thereby excluding data generated by the rest of the larger TIN, in cases where the APM Entity itself performed above average relative to the rest of that TIN.

Therefore, we are proposing to introduce a voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the 2023 performance period. Multi-TIN APM Entities that do not choose this proposed new reporting option would continue to be scored using the roll -up calculation described at § 414.1317(b)(1). We seek comment on this proposal.

e. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act provides, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards for a performance period and use such methodology to provide for a composite performance score for each such clinician for each performance period.

For the CY 2023 performance period/ 2025 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. We believe that this scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We are proposing to update our scoring policies consistent with this framework. Specifically, we are proposing to—

- Amend the benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data.
- Clarify the topped-out measure policy and update the topped-out measure life cycle for scoring topped-out measures in the quality performance category.
- Establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year.

We refer readers to section IV.A.10.c.(4)(l) of this proposed rule for our proposed changes to the scoring methodology for the Promoting Interoperability performance category. We are not proposing changes to scoring policies for the improvement activities performance category.

We refer readers to § 414.1380 for our current policies on scoring.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our current policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913). In the CY 2022 PFS final rule we finalized policies to simplify scoring in MIPS as we transition to MVPs and to incentivize the selection of new, potentially high-value measures (86 FR 65496 through 65507).

(i) Scoring Administrative Claims Measures in the Quality Performance Category Using Performance Period Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 Quality Payment Program final rules and PFS final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, 84 FR 63014 through 63016, and 85 FR 84901 through 84904, respectively) for our previously established benchmarking policies.

In the CY 2017 Quality Payment Program final rule (81 FR 77276 through 77282), we finalized a rule providing that we will use MIPS eligible clinicians' performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period. In these cases, we will calculate benchmarks using data submitted during the applicable performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for the CY 2023 performance period/2025 MIPS payment year, the baseline period two performance periods prior would be the CY 2021 performance period (81 FR 77276 and 77277). Additionally, in the CY 2019 PFS final rule (83 FR 59842), we amended § 414.1380(b)(1)(ii) to align our benchmark policy with concurrently made changes to our date submission terminology. These changes removed references to each individual benchmark and instead stated that benchmarks will be based on measure collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Additionally, we refer readers to the CY 2017 Quality Payment Program final rule and the CY 2021 PFS final rule (81 FR 77130 through 77136 and 85 FR 84871 through 84873 respectively) and § 414.1325(a)(2)(i) for our previously established policies regarding administrative claims measures in the quality performance category.

The policy at § 414.1325 provides that there is no data submission requirement for cost measures or administrative claims measures in the quality performance category as these measures are calculated on behalf of participants by CMS using administrative claims data. In the CY 2017 Quality Payment Program final rule, we finalized a policy that clinicians would be scored on applicable administrative claims-based global or population health (henceforth referred to only as population health measures) in addition to the six required submitted measures. Additionally, we established exclusions to the case minimum policy of 20 cases. It was found that the all-cause hospital readmission (ACR) measure was not reliable for cases under 200 and for groups of fewer than ten clinicians. As a result, we established exceptions to the case minimum policy for this measures and others as specified in the MIPS final list of quality measures through rule making (§ 414.1380(b)(1)(iii)). In the CY 2021

PFS final rule (85 FR 84989 through 84901), we finalized a policy starting in the CY 2021 performance period/2023 MIPS payment year that would allow for performance periods longer than the standard 12-month performance period for administrative claims measures in the cost and quality performance categories as specified through rulemaking.

Beginning with the CY 2023 performance period/2025 MIPS payment year, we are proposing that we will score administrative claims measures using benchmarks calculated using performance period benchmarks. We believe that using a performance period benchmark to score these measures would allow for scores that are more reflective of current performance, while adding no additional burden to clinicians. For the reasons described below, we believe it is more appropriate in certain circumstances to evaluate clinicians against current performance benchmarks. As previously noted, they do not require the submission of data by or on behalf of clinicians and may have a measure-specific performance period to ensure appropriate sample sizes. Additionally, in instances where these measures do not meet the case minimum or benchmark requirements, they are excluded from a MIPS-eligible clinician's quality performance category score.

The use of performance period benchmarks for such measures would help us to improve quality measurement. For example, the Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) has a 3-year performance period (consecutive 36-month timeframe) [524] that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, proceeding with a 3-month numerator assessment period (capturing complication outcomes) followed by a 2-month claims run-out period. For the CY 2023 performance period/2025 MIPS payment year, the 3-year (36 consecutive months) performance period for this measure would span from October 1, 2020 to September 30, 2023 with a 90-day numerator assessment period followed by a 60-day claims run-out period. This means that according to standard scoring policy, the corresponding baseline would include data from October 1, 2018 to September 30 2021. We believe that comparison to data that precedes that standard 2-year baseline period may limit the usefulness of this measure. By comparing performance to data that was collected 5 years prior, this measure does not account for changes to the healthcare landscape and improvements in care that might have been made in the timeframe.

We do not believe using performance period benchmarks would increase burden to clinicians. We believe that clinicians prefer to have historical benchmarks to aid in measure selection and have performance targets. Additionally, population health administrative claims measures in MIPS are not subject to case minimum policies reducing the risk in being scored on these measures.

Accordingly, we are proposing to add a paragraph at § 414.1380(b)(1)(ii)(D) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims quality measure using the performance on the measure during the current performance period. We note that we do not intend this proposal to modify our existing policies regarding case minimums and measures for which no benchmark may be calculated. Specifically, measures would remain subject to case minimum requirements described in paragraph (b)(1)(iii) and benchmark requirements in paragraph (b)(1)(ii)(A) of this section. Measures that cannot have a benchmark calculated or meet case minimum requirements would still be deducted from the eligible clinician's total measure achievement points consistent with (b)(1)(i)(A)(*2*)(*ii*).

We are seeking public comment on our proposals to score administrative claims measures in the quality performance category using performance period benchmarks.

(ii) Assigning Measure Achievement Points for Topped Out Measures

Section 1848(q)(3)(B) of the Act requires that, in establishing performance standards with respect to measures and activities, the Secretary consider, among other things, the opportunity for continued improvement. As part of our implementation of section 1848(q)(3)(B) of the Act, we established our topped out measure policy, which is intended to encourage clinicians to focus on areas where clinical improvement is necessary possible by capping the points received for reporting on MIPS measures where meaningful distinctions in clinical performance are no longer measurable. We refer readers to § 414.1380(b)(1)(iv)(B) for our policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we identify topped out measures in the benchmarks published for each performance year. Under § 414.1380(b)(1)(iv)(B), beginning with the CY 2019 performance period/2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 and 53727).

We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77286) that we would define topped out process measures as those with a median performance rate of 95 percent or higher (§ 414.1305). We defined topped out non-process measures using a definition similar to the definition used in the Hospital Value-Based Purchasing (VBP) Program: a measure where the truncated coefficient of variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors (81 FR 77286). When a measure is topped out, a large majority of clinicians submitting the measure perform at or very near the top of the distribution; therefore, there is little or no room for the majority of MIPS eligible clinicians who submit the measure to improve. We understand that each measure we have identified as topped out may offer room for improvement for some MIPS eligible clinicians; however, we believe asking clinicians to submit measures that we have identified as topped out and measures for which the vast majority of MIPS eligible clinicians already excel is an unnecessary burden that does not add value or improve beneficiary outcomes.

In the CY 2018 Quality Payment Program final rule, we finalized that, beginning in the CY 2019 performance period/2021 MIPS payment year, each measure (excluding measures in the CMS Web Interface) that is identified as topped out for two or more consecutive years can receive no more than 7 points in the second year that it is identified as topped out and beyond (82 FR 53726 through 53727). A measure is identified as topped out for a given performance period by assessing its historical benchmark. Two consecutive historical

[524] Section 414.1320(e)(1) provides in relevant part that, beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures.

benchmarks must be labeled as topped out for the 7-point cap to be applied for a given performance period. For example, for the CY 2023 performance period/2025 MIPS payment year, a measure is considered topped out if the historical benchmark calculated from data submitted in the CY 2021 performance period has a median performance of 95 percent or higher in the case of process measures or the truncated coefficient of variation is less than 0.10 and the 75th and 90th percentiles are within two standard errors in the case of non-process measures. If this same measure is identified as topped out again for the CY 2024 performance period/2026 MIPS payment year from data from the historical baseline period from CY 2022, this measure would be labeled as topped out and have the 7-point cap applied until the historical baseline period shows that the measure is no longer topped out or the measure is removed from the program. We believe this methodology incentivizes MIPS eligible clinicians to begin submitting non-topped out measures without performing below the median score. The methodology also does not impact scoring for those MIPS eligible clinicians that do not perform near the top of the measure, and therefore, have significant room to improve on the measure.

In the CY 2021 PFS final rule (85 FR 84989 through 84901), we finalized a policy at § 414.1380(b)(1)(vii)(A) that consolidated previously established scoring flexibilities regarding the truncation of a quality measure's performance period to 9-months of data from the CY 2018 Quality Payment Program final rule (82 FR 52714 through 53716) and the measure suppression policy established in the CY 2019 PFS final rule (FR 59845 through 59847). The updated scoring flexibilities policy stated that, beginning with the CY 2021 performance period/2023 MIPS payment year, CMS would truncate the performance period or suppress a quality measure if CMS determined that revised clinical guidelines, measure specifications, or codes impacted a clinician's ability to submit information on the measure or may lead to potentially misleading results (85 FR 84899 through 84901). We stated that, based on the timing of the changes to clinical guidelines, measure specifications or codes, we will assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we will suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted (85 FR 84899). In the CY 2022 PFS final rule (86 FR 65491 and 65492), the scope of the truncation and suppression policy was expanded to include errors that are outside the control of the clinician, such as an incorrect coding status.

We now clarify the interaction of our topped-out measure policy and our measure truncation and measure suppression policies. First, we must note that not all instances in which a measure lacks a benchmark affect the scoring of the measure equally. For example, when a measure is suppressed in the baseline period for the incorrect inclusion of an inactive status code in the measure specifications, the measure could resume to be scored comparably once the measure specifications are accurate in both the baseline and applicable performance period. Conversely, a measure that was suppressed or had its performance period truncated because it underwent a substantive change could not be comparably scored. In a case like the former, it is not until the suppressed or otherwise affected data is in the baseline period that the topped-out measure lifecycle is affected. A measure that lacks a benchmark for a performance period due to the suppression of date in the measure's baseline period will not have the 7-point cap applied for that performance period. This is because the measure lacks the two topped out historical performance periods necessary for the application of the cap. This does not preclude, however, CMS determining that the measure is topped out for the performance period. In the case of a measure that lacks a baseline period, CMS may base the benchmark on performance during the applicable performance period (*See* § 414.1380(b)(1)(ii)). Determining the measure was topped out during the performance period would thus require only that MIPS eligible clinician data for the performance period met the topped-out measure standard. In such a case, the 7-point cap could next be applied as soon as the following year.

Where a measure was suppressed or had its performance period truncated because of a substantive change or a change in clinical guidelines, the topped-out measure resets entirely the year following the change as there is no longer a historical benchmark with which to compare the measure for the purpose of determining whether it is topped out.

(c) Cost Performance Category Score

(i) Improvement Scoring Methodology

In the CY 2018 Quality Payment Program final rule, we established policies related to measuring improvement in the cost performance category at the measure level, an improvement scoring methodology for the cost performance category, and a formula for calculating the cost performance category percent score to include achievement and improvement (82 FR 53748 through 53752). These policies were to apply beginning with the CY 2018 performance period/2020 MIPS payment year. We codified these policies under § 414.1380(b)(2)(iii) and (iv) (82 FR 53748 through 53752, 53957). Subsequent to the publication of that final rule, the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123, enacted February 9, 2018) was enacted. Section 51003(a)(1)(B) of the BBA 18 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take in to account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. In the CY 2019 PFS proposed rule, we stated that we do not believe this statutory change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category percent score for each of the CY 2020 through 2023 MIPS payment years (83 FR 35956). Therefore, we proposed to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the CY 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points (83 FR 35956). We stated that under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the CY 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under our proposal, the maximum cost improvement score for the CY 2020 MIPS payment year would be zero percentage points (83 FR 35956). We also proposed at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take in to account improvement until the CY 2024 MIPS payment year (83 FR 35956). In the CY 2019 PFS final rule, we finalized these proposals as proposed (83 FR 59856).

In prior rulemaking, we inadvertently failed to address what the maximum cost improvement score would be under

§ 414.1380(b)(2)(iv)(E) beginning with the CY 2022 performance period/2024 MIPS payment year. As we stated previously in the CY 2019 PFS proposed and final rules (83 FR 35956 and 83 FR 59856, respectively), we do not believe the changes made to section 1848(q)(5)(D) of the Act by section 51003(a)(1)(B) of the BBA 18 required us to remove our existing methodology for scoring improvement in the cost performance category. Thus, in the CY 2019 PFS final rule, we maintained the methodology we had previously established under § 414.1380(b)(2)(iii) and (iv), while modifying § 414.1380(b)(2)(iv)(E) to reflect the statutory change made by section 51003(a)(1)(B) of the BBA 18. Section 1848(q)(5)(D) of the Act requires us to take in to account the improvement of the MIPS eligible clinician when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year) and for subsequent years. We are proposing to establish a maximum cost improvement score of 1 percentage point for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year. A maximum cost improvement score of 1 percentage point was the policy we established previously, before the amendments made by section 51003(a)(1)(B) of the BBA 18 with respect to the second, third, fourth, and fifth years of MIPS. We believe this policy is still appropriate at this time because although there are many opportunities for clinicians to actively work on improving their performance on cost measures, such as through more active care management or reductions in certain services, we recognize that many clinicians are still learning about cost measurement under MIPS. We aim to continue to educate clinicians about cost measurement and develop opportunities for robust feedback and measures that better recognize the role of clinicians. Clinicians are navigating and overcoming the obstacles of the COVID–19 public health emergency while having to familiarize themselves with new policies we have adopted for MIPS, such as the establishment of MVPs as a voluntary means for participation starting with the CY 2023 performance period that could become a mandatory means of participation, the opportunity for subgroup participation and reporting, the sunset of the CMS Web Interface as a collection/submission type and transition to other collection and submission types for CMS Web Interface users starting with the CY 2023 performance period, and the implementation of new cost measures. As the CY 2022 performance period/2024 MIPS payment year is the first program year we will be measuring improvement for the cost performance category, we believe it would be appropriate to begin gradually with a maximum cost improvement score of 1 percentage point—a policy clinicians already would be familiar with from prior rulemaking. In a future year, we may consider and assess the possibility of increasing the maximum cost improvement score.

To the extent that this proposed change constitutes a change to the MIPS scoring or payment methodology for the CY 2024 MIPS payment adjustment after the start of the CY 2022 performance period, we believe that, consistent with section 1871(e)(1)(A)(i) of the Act, it is necessary to comply with the requirement of section 1848(q)(5)(D) of the Act that we take in to account the improvement of the MIPS eligible clinician when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year). We also believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to fill the gap in our existing methodology for scoring improvement in the cost performance category for the CY 2022 performance period/2024 MIPS payment year. Currently, our improvement scoring methodology for the cost performance category under § 414.1380(b)(2)(iv)(E) does not include a maximum cost improvement score for the CY 2022 performance period/2024 MIPS payment year. Our proposal would correct this deficiency by establishing a maximum cost improvement score of 1 percentage point beginning with the CY 2022 performance period/2024 MIPS payment year. In addition, it would be contrary to the public interest not to comply the statutory requirement of section 1848(q)(5)(D) of the Act to take in to account improvement when scoring the cost performance category for the sixth year of MIPS (the CY 2022 performance period/2024 MIPS payment year).

We are proposing corresponding changes to § 414.1380(b)(2)(iv)(E) to reflect the proposal. We solicit public comment on the proposal.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for each MIPS eligible clinician, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, respectively) on final score calculations, performance category weights, reweighting the performance categories, and the complex patient bonus.

As described in more detail in the following sections, we:

- Propose that a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus.
- Request information on which additional risk indicators and data sources we should consider for use within the complex patient bonus formula to better assess the social and medical complexity for the patients of MIPS eligible clinicians.
- Propose that virtual groups would be eligible for facility-based measurement.
- Propose changes to the definition of a facility-based MIPS eligible clinician.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021, 2022, and 2023 MIPS payment

years (83 FR 59870, 84 FR 63023, and 85 FR 84910, respectively). Additionally, we finalized for the 2022 and 2023 MIPS payment years at § 414.1380(c)(3)(iv) that the complex patient bonus will be calculated under the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2, but cannot exceed 10.0 (85 FR 84911 through 84913 and 86 FR 65510 and 65511, respectively). Finally, beginning with the CY 2022 performance period/2024 MIPS payment year, we revised the complex patient bonus by: (1) limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (Hierarchical Condition Category (HCC) and dual proportion); (2) standardizing the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients; and (3) providing one overall complex patient bonus cap at 10 bonus points (86 FR 65511 through 65519). We refer readers to the final rules cited above for additional details on the background, statutory authority, policy rationale, and calculation of the complex patient bonus.

(ii) Eligibility for the Complex Patient Bonus

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1380(c)(3) a complex patient bonus for MIPS eligible clinicians, groups, APM Entities, and virtual groups that submit data for at least one MIPS performance category during the applicable performance period, which will be added to the final score (82 FR 53771 through 53776). In the CY 2018 Quality Payment Program proposed rule, we proposed that a MIPS eligible clinician, group, virtual group or APM Entity must submit data on at least one measure or activity in a performance category during the performance period to receive the complex patient bonus (82 FR 30138). We stated that under this proposal, MIPS eligible clinicians would not need to meet submission requirements for the quality performance category to receive the bonus (they could instead submit improvement activities or Promoting Interoperability performance category measures only or submit fewer than the required number of measures for the quality performance category). In the CY 2018 Quality Payment Program final rule, we also established facility-based measurement for certain MIPS eligible clinicians under the authority in section 1848(q)(2)(C)(ii) of the Act, which provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories (82 FR 53752 through 53767). We did not address whether facility-based MIPS eligible clinicians would be eligible to receive the complex patient bonus. Under the scoring methodology for facility-based measurement under § 414.1380(e), there are no data submission requirements for individual clinicians to be scored under facility-based measurement (§ 414.1380(e)(4)). Although individual facility-based MIPS eligible clinicians are not required to submit data for at least one MIPS performance category, and it is possible they may choose not to submit data voluntarily, we believe they should be eligible to receive the complex patient bonus. As with other MIPS eligible clinicians who submit data for the quality performance category, we are able to score this performance category for facility-based MIPS eligible clinicians based on quality measure data available to us pursuant to the methodology described under § 414.1380(e). Thus, we are proposing that beginning with the 2023 performance period/2025 MIPS payment year, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category. We are proposing corresponding revisions to § 414.1380(c)(3). We seek comments on this proposal.

(iii) Request for Information on Risk Indicators for the Complex Patient Bonus Formula

(A) Background on Risk Indicators Within the Complex Patient Bonus Formula

In the CY 2022 PFS final rule, we finalized to continue using the existing risk indicators for the complex patient bonus formula (86 FR 65511 through 65517). We received comments regarding our policy to continue to use the existing risk indicators. A few commenters requested that CMS look at additional risk indicators to account for additional complexities within the complex patient bonus formula. Specifically, a few commenters suggested CMS consider clinical data to capture comorbidities and alternatives to dual eligibility to capture social risk. Other commenters suggested CMS consider using other data such as Z-codes and indices (for example, Social Vulnerability Index, Community Needs Index, etc.). In response to these comments, we stated that we would take the comments into consideration as we continue updating the complex patient bonus in future years (86 FR 65517). We also stated that, although the HHS Assistant Secretary for Planning and Evaluation (ASPE) report found dual eligibility to be a reliable indicator of social risk, we understand there may be some limitations.[525] However, at that time, we were unaware of data sources and/or methodologies to account for other social indicators such as income and education which are readily available for all Medicare beneficiaries and would be more complete indices of a patient's complexity. We stated that we continue to believe that average HCC risk scores are a valid proxy for medical complexity which are also used by other CMS programs. Therefore, we stated that we will continue to pair the HCC risk score with the proportion of dually eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We stated that we will evaluate additional, more comprehensive options, such as Z-codes and indices, based on any updated data or additional information, including to better account for social risk factors while minimizing unintended consequences.

When we considered the approaches for a complex patient bonus in the CY 2018 Quality Payment Program proposed rule (82 FR 30135 through 30139), we reviewed evidence to identify how indicators of patient complexity have an impact on performance under MIPS as well as availability of data to implement the bonus, described in more detail in the regulatory impact analysis of the CY 2018 Quality Payment Program proposed rule (82 FR 30235 through 30238). At that time, we identified two potential indicators for complexity: medical complexity as measured through HCC risk scores and social risk as measured through the proportion of patients with dual eligible status. We identified these indicators because they are common indicators of patient complexity in the Medicare program and the data is readily available. Please refer to the CY 2018 Quality Payment Program proposed rule for a detailed discussion of our analysis of both indicators that informed our proposal (82 FR 30135 through 30138). Specifically, we proposed (82 FR 30138) and finalized (82 FR 53776) at § 414.1380(c)(3)(i) to calculate an

[525] ASPE. Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 29, 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

average HCC risk score, using the model adopted under section 1853 of the Act for Medicare Advantage risk adjustment purposes, for each MIPS eligible clinician or group, and to use that average HCC risk score as the complex patient bonus.

Additionally, in the CY 2019 PFS final rule (83 FR 59870), we finalized to calculate the average HCC risk score for a MIPS eligible clinician or group by averaging HCC risk scores for beneficiaries cared for by the MIPS eligible clinician or clinicians in the group during the second 12-month segment of the eligibility period, which begins on October 1 of the calendar year preceding the applicable performance period and ends on September 30 of the calendar year in which the applicable performance period occurs. Beginning with the 2021 MIPS payment year, the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) is used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

(B) Request for Information on Risk Indicators Within Complex Patient Bonus Formula to Continue to Align With CMS Approach to Operationalizing Health Equity

CMS defines ''health equity'' as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, social economic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive. We focus our health equity actions in five high-impact areas based on input from interested parties and communities, which incorporate both community- and system-level approaches to achieving health equity.[526]

- Expand the Collection, Reporting, and Analysis of Standardized Data;
- Assess Causes of Disparities Within CMS Programs and Address Inequities in Policies and Operations to Close Gaps;
- Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities;
- Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services; and
- Increase All Forms of Accessibility to Health Care Services and Coverage.

We believe the complex patient bonus aligns with all five focus areas, addressing the need for standardized data collection, supporting CMS in addressing inequities to close gaps, and helping build capacity among health care professionals to provide tailored, culturally and linguistically appropriate, accessible care that meets their patients' needs and addresses social risk factors that individuals experience which can affect health care quality, access, and outcomes. To ensure our focus remains on the communities, individuals, and health care professionals we serve, we continue to explore ways and efforts to improve our current policies to advance health equity in ways that are responsive to the needs of our interested parties.

In section III.G.4.b.(7)(d) of this rule, we are proposing a positive adjustment to the quality performance score for an Accountable Care Organizations (ACO) that achieves a specified level of quality performance and serves beneficiaries in areas with a high Area Deprivation Index (ADI) or serves a large proportion of dual eligible beneficiaries. At this time, we are evaluating and inquiring whether the ADI measure is a good indicator of beneficiaries with high needs for use within the MIPS program as it is intended to capture local socioeconomic factors correlated with medical disparities and underservice. ADI is now reported publicly through the Neighborhood Atlas from the University of Wisconsin. It is a relative measure that is reported at the individual level, typically reported by percentile (1–100) or decile (1–10), with a higher percentile indicating greater disadvantage.

While we are not currently proposing to use the ADI measure within the complex patient bonus, we ask for public comments on the potential future incorporation of the measure. We are particularly interested in information from, or related to perspectives of, individuals living in or serving underserved communities, including health care professionals disproportionately serving underserved communities and medically and socially complex patients:

- What additional risk indicators should CMS consider incorporating within the complex patient bonus formula?

++ How should CMS incorporate those additional risk indicators into the complex patient bonus formula?

++ What additional data sources should CMS consider that would allow for CMS to calculate the complex patient bonus in both a feasible and timely manner?

++ What additional measures or indicators are already developed which may capture the social determinants of health?

- In considering a potential future definition of ''safety net providers'' in the context of the complex patient bonus, CMS is interested in input and information related to the definition of ''Essential Community Providers'' (ECPs) as defined in 45 CFR 156.235. Under that regulation, ECPs are defined as providers that serve predominantly low-income, medically underserved individuals. They include covered entities defined in section 340B(a)(4) of the Public Health Service (PHS) Act and entities described in section 1927(c)(1)(D)(i)(IV) of the Act. Additional providers may submit an online petition to be considered and approved by CMS for inclusion on the ECP list through the ECP petition review process. We are interested in information from commenters regarding:

++ Whether the definition of ''essential community providers'' adequately functions as a potential definition for safety net providers and could include all MIPS eligible clinicians who may receive the complex patient bonus? What (if any) concerns would health care providers or health care professionals have regarding the use of this definition?

++ What recommendations for alternate definitions should CMS consider as a definition of ''safety net provider'' that would be inclusive of all MIPS eligible clinicians who may receive the complex patient bonus?

++ When considering the ''safety net provider'' definition, how would commenters suggest CMS consider differences related to location or facilities that might qualify as ''safety net providers'' versus individual health care professionals who might also qualify as ''safety net providers''? What would commenters identify as key determinations when considering a location, site-based, or facility-based definition or an individual health care

[526] *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity.*

professional based definition of ''safety net provider'' in the context of MIPS eligible clinicians who may receive the complex patient bonus?

(b) Facility-Based Measurement

(i) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767), we established facility-based measurement under the authority in section 1848(q)(2)(C)(ii) of the Act for certain MIPS eligible clinicians. We established facility-based measurement to better align incentives between facilities and the MIPS eligible clinicians who provide services there (82 FR 53753). Scoring under facility-based measurement was available for clinicians beginning with the CY 2019 performance period/2021 MIPS payment year. In the CY 2022 PFS final rule, we finalized at § 414.1380(e)(6)(vi)(B) that for clinicians and groups eligible for facility-based measurement, beginning with the CY 2022 performance period/2024 MIPS payment year, the MIPS quality and cost performance category scores for such clinicians and groups will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission (86 FR 65526 and 65527). For more background on facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767), the CY 2019 PFS final rule (83 FR 59856 and 59867), the CY 2020 PFS final rule (84 FR 63018 through 63020), and the CY 2022 PFS final rule (86 FR 65526 and 65527).

(A) Eligibility for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53756 and 53757), we finalized individual eligibility criteria for facility-based measurement at § 414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service (POS) codes used in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS is eligible as an individual for facility-based measurement. We specified that we would use the definition of professional services provided in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). In the CY 2019 PFS final rule, we added the on-campus outpatient hospital (POS code 22) to the list of sites of service we consider when determining eligibility for facility-based measurement (83 FR 59857 through 59860). Additionally, we required that clinicians bill at least one covered professional service in a site of service identified by the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement. We codified these standards in § 414.1380(e)(2)(i)(A) and (B). We also finalized that we must be able to attribute a clinician to a particular facility that has a value-based purchasing score under the methodology specified in § 414.1380(e)(5) in order for the clinician to be eligible for facility-based measurement (§ 414.1380(e)(2)(i)(C)).

Separately, in the CY 2018 Quality Payment Program final rule (82 FR 53759), we defined a facility-based group as a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements described above.

As we clarified and expanded our definition of a facility-based MIPS eligible clinician, we intended to allow MIPS eligible clinicians participating in virtual groups to be eligible for facility-based measurement using the same standards applicable to individual MIPS eligible clinicians and groups. We intended this because, just like individual clinicians and groups, some virtual groups may predominantly practice within a hospital setting and their MIPS eligible clinicians may otherwise be eligible for facility-based measurement based on the eligibility standards established at § 414.1380(e)(2)(i)(A) through (C) were they to participate in MIPS individually or as a group. However, we did not specify at § 414.1380(e)(2) that virtual groups may be eligible for facility-based measurement. Therefore, we are proposing to revise § 414.1380(e)(2) to permit facility-based measurement of a virtual group so long as it meets the specified eligibility standards beginning with the 2023 performance period/2025 MIPS payment year. Additionally, we are also proposing to revise § 414.1380(e)(2) to specify, consistent with our prior discussion of the matter, that a MIPS eligible clinician is eligible for facility-based measurement only if CMS determines it eligible to be facility-based (82 FR 53757). We seek comments on this proposal.

(B) Definition of Facility-Based MIPS Eligible Clinician

In the CY 2018 Quality Payment Program final rule, we finalized the definition of a facility-based MIPS eligible clinician at § 414.1305 (82 FR 53578). In the CY 2019 PFS final rule, we finalized additions to the determination of eligibility for facility-based measurement as reflected in the regulation text at § 414.1380(e)(2)(i)(A), (B), and (C) (83 FR 59856 through 59860); however, we inadvertently did not update the definition of a facility-based MIPS eligible clinician at § 414.1305 to reflect these additions. Therefore, we are proposing to revise the facility-based MIPS eligible clinician definition at § 414.1305 to align with the current policies at § 414.1380(e)(2)(i)(A), (B), and (C), which are described in detail in section IV.A.10.d.(2)(b)(i)(A) of this proposed rule. We are also proposing to revise the terminology within § 414.1380(e) to align with the terminology used in the definition of a facility-based MIPS eligible clinician at § 414.1305. We are seeking comments on these proposals.

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used to determine MIPS payment adjustments, we refer readers to the CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In this CY 2023 PFS proposed rule, we are proposing to establish the performance threshold for the CY 2025 MIPS payment year using 2019 MIPS payment year data. In addition, we are including information about our timing for providing MIPS performance feedback to clinicians for the performance period in 2021.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a

year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which required the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

We applied these special rules for the first 5 years of MIPS to provide for a gradual and incremental transition to the performance we estimated for the sixth year of MIPS (the CY 2024 MIPS payment year). In the CY 2022 PFS final rule, we set the performance threshold at 75 points for the CY 2024 MIPS payment year (86 FR 65532). For further information on the performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53794), CY 2019 PFS final rule (83 FR 59880 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), and CY 2022 PFS final rule (86 FR 65527 through 65532). We codified the performance thresholds for each of the first 6 years of MIPS at § 414.1405(b)(4) through (9), as shown in Table 89.

TABLE 89: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year
Performance	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
Threshold	3 points	15 points	30 points	45 points	60 points	75 points
Difference in Performance Threshold (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points	15 points

Beginning with the CY 2024 MIPS payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every 3 years. In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for determining the performance threshold for each of the 2024, 2025, and 2026 MIPS payment years. We intend to reassess and establish the methodology (mean or median) that we will use to determine the performance threshold for each of the next 3 years (2027 MIPS payment year, 2028 MIPS payment year, and 2029 MIPS payment year) in future rulemaking.

While we identified the mean as our methodology for determining the performance threshold for MIPS payment years CY 2024 through 2026, we have not specified which prior period's mean final score we would use for the 2025 MIPS payment year's performance threshold. From our review of the data available to us, we have identified the mean final scores for each of the 2019 through 2022 MIPS payment years, as shown in Table 90. These four values represent the mean final scores for all MIPS eligible clinicians from prior periods that are available for consideration for the CY 2025 MIPS payment year performance threshold. The final scores for the CY 2021 MIPS performance period/2023 MIPS payment year were not finalized in time for this proposed rule; thus, the mean final score for the CY 2023 MIPS payment year is not listed as a potential performance threshold value for the CY 2025 MIPS payment year.

TABLE 90: Possible Values for the 2025 MIPS Payment Year Performance Threshold

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year
Mean	74.65 Points	87 Points	85.63 Points	89.47

As shown in Table 90, the mean final scores available for consideration for the CY 2025 MIPS payment year performance threshold cover a range of values from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). We are proposing to use the CY 2019 MIPS payment year as the prior period for the purpose of determining the performance threshold for the CY 2025 MIPS payment year for several reasons. We expect the mean final score for the CY 2023 performance period/2025 MIPS payment year to be lower than the mean final scores from the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. In the CY 2022 PFS final rule (86 FR 65491 through 65507), we removed transition policies such as quality bonus points that had been established for scoring the quality performance category for the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. Additionally, for the CY 2019 through 2021 performance periods/2021 through 2023 MIPS payment years, we applied certain extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which resulted in the reweighting of some performance categories if data were not submitted for a MIPS eligible clinician. In setting the performance threshold for the CY 2025 MIPS payment year, we believe we should take into account the elimination of those transition policies, as well as the possibility that the performance categories will not be reweighted for as many MIPS eligible clinicians for the CY 2023 performance period/2025 MIPS payment year. Furthermore, continuing to use the mean final score from the CY 2019 MIPS payment year to determine the performance threshold for the CY 2025 MIPS payment year would maintain stability in the program. We believe continuing to use the mean final score from the CY 2019 MIPS payment year would provide predictability to MIPS eligible clinicians during a program year in which they might be affected by those prior policy changes as well as potentially scored on performance categories that were previously reweighted due to the COVID–19 PHE.

We estimate in the Regulatory Impact Analysis (RIA) in section VII.E.16.d.(4) of this proposed rule that approximately a third of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2023 performance period/2025 MIPS payment year if the policies proposed in this proposed rule are finalized and the performance threshold is equal to 75 points. However, we have estimated that final scores for many clinicians for the CY 2023 performance period/2025 MIPS payment year would be close to the proposed performance threshold of 75 points; therefore, the actual observed percentage of clinicians receiving negative payment adjustments may slightly differ from the RIA estimates. We refer readers to the alternatives considered in the RIA in section VII.F.7 of this proposed rule where we present the impact of using data from alternative years to determine the performance threshold for the 2025 MIPS payment year. We intend to revisit in future rulemaking whether we should use a different prior period to establish the performance threshold for future MIPS payment years.

Under this proposal, and pursuant to the methodology we established previously at § 414.1405(g), the performance threshold for the CY 2025 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2019 MIPS payment year, which is 75 points (rounded from 74.65 points). We propose corresponding changes to § 414.1405(b)(9) to reflect this proposal. We request comments on this proposal, as well as whether we should use data from alternative years to set the performance threshold for the CY 2025 MIPS payment year, which we considered and discussed in the RIA in section VII.F.7 of this proposed rule.

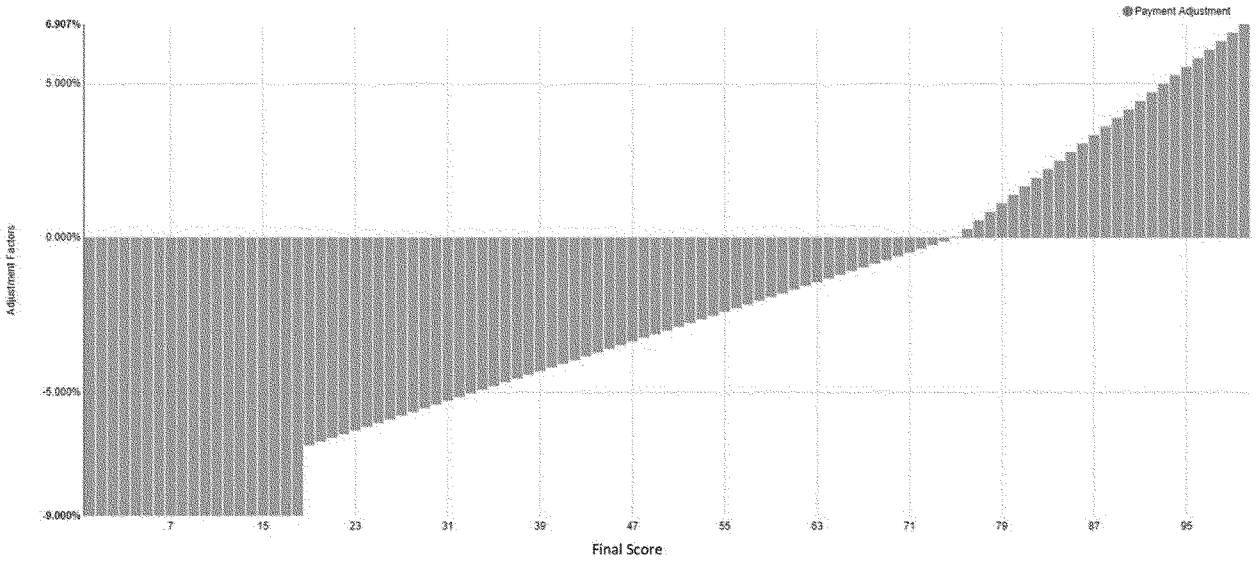
(3) Example of Adjustment Factors

Figure 4 provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2025 MIPS payment year. In Figure 4, the performance threshold is set at 75 points. The applicable percentage is 9 percent for the CY 2025 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the CY 2025 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the performance threshold of 75 points for the CY 2025 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive the lowest negative applicable percentage (negative 9 percent for the CY 2025 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 75 points (which is the proposed performance threshold for the CY 2025 MIPS payment year) would receive a neutral MIPS payment adjustment. Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act will no longer be available. For this reason, Figure 4 no longer illustrates an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

Figure 4: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Proposed Performance Threshold for the 2025 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN), but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 91 illustrates the changes in payment adjustment based on the final policies from the CY 2022 PFS final rule (86 FR 65527 through 65536) for the 2024 MIPS payment year and the proposed policies for the 2025 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 91: Illustration of Point System and Associated Adjustments Comparison between the 2024 MIPS Payment Year and the Proposed 2025 MIPS Payment Year

2024 MIPS Payment Year		2025 MIPS Payment Year	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.0	0% adjustment	75.0	0% adjustment
75.01-88.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.
89.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 89.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance		

f. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

As we explained previously, we aim to provide performance feedback on or around July 1 of each year, but due to the PHE and COVID–19, it is possible that we might provide performance feedback at a later date (85 FR 50321). We made performance feedback available for the CY 2019 performance period on August 5, 2020, and for the CY 2020 performance period on August 2 and September 27, 2021. Although we aim to provide performance feedback for the CY 2021 performance period on or around July 1, 2022, it is possible that the release date could be later depending on the circumstances. We direct readers to *qpp.cms.gov* for more information.

g. Third Party Intermediaries General Requirements

(1) General Requirements

(a) Background

Flexible reporting options will provide eligible clinicians with options

to accommodate different practices and make measurement meaningful. We believe that allowing eligible clinicians to participate in MIPS through the use of third party intermediaries that will collect or submit data on their behalf, will help us accomplish our goal of implementing a flexible program (82 FR 53806).

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), and the CY 2022 PFS final rule (86 FR 65538 through 65550) for our previously established policies regarding third party intermediaries.

In this proposed rule, we are proposing to update the definition of a third party intermediary at § 1400.1305 and to make other minor conforming technical edits to the regulation text governing third party intermediaries set forth in § 414.1400. We are also proposing to revise Qualified Clinical Data Registry (QCDR) measure self-nomination and measure approval requirements, including proposing to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year. We are also proposing to revise remedial action and termination of third party intermediaries' policies. Finally, we have also included two requests for information on third party intermediary support of MIPS value pathways (MVPs) and national Continuing Medical Education (CME) organizations becoming a new type of third party intermediary.

(b) Definition of a Third Party Intermediary

In the CY 2022 PFS final rule (86 FR 65542 through 65545), we finalized at § 414.1400(a)(1) that MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or Alternative Payment Model (APM) Entity by any of the following third party intermediaries: QCDR; qualified registry; health IT vendor; or CMS approved survey vendor. In that rule, we added APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third party intermediaries reporting MIPS on behalf of APM Entities (86 FR 65542). We also revised § 414.1400(a)(1) to allow for QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, a recently adopted option for MIPS eligible clinicians reporting MIPS Value Pathways (86 FR 65544 through 65545). One of our strategic goals in developing MIPS included developing a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians. One way we believe this could be accomplished is through flexible reporting options, including allowing MIPS eligible clinicians the flexibility of using third party intermediaries to collect or submit data on their behalf. In the CY 2019 PFS final rule (83 FR 59894) we finalized at § 414.1305 to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

We now propose to update the definition of a third party intermediary at § 414.1305 to include subgroups and APM Entities and to make minor edits for technical clarity. We propose the revised definition would state that a third party intermediary means an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. We request comments on this proposal.

(2) Requirements Specific to QCDRs

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(B)(ii) of the Act provides, that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of certified EHR technology and qualified clinical data registries.

We believe QCDRs and QCDR measures further health equity through the expansion of data collection, reporting, and analysis. QCDR measures data can be used not only to identify gaps in the standard of care, but also to determine solutions to disparate impacts on different populations. We anticipate growth in the number of QCDR measures that address health equity in upcoming performance years. We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 through 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944) and the CY 2022 PFS final rule (86 FR 65540 through 65550) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

(b) QCDR Measure Self-Nomination Requirements

As part of QCDR measure self-nomination, § 414.1400(b)(4)(i) and (b)(4)(i)(B) require the nominating QCDR to publicly post the QCDR measure specifications (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted no later than 15 calendar days following CMS approval. We typically notify a QCDR of its measure's approval prior to our posting of the approved measure specifications. While we require QCDRs to post their approved measure specifications, as their websites are an important source for clinicians, we want to limit the chance of discrepancies between CMS's posting and QCDRs' postings.

To avoid confusion, we are proposing to revise § 414.1400(b)(4)(i)(B) to clarify requirements for publicly posting the approved measure specifications. Specifically, we propose to revise the language such that entities must publicly post measure specifications no later than 15 calendar days following CMS's posting of approved QCDR measure specifications on a CMS website and that QCDRs need to confirm that the measure specifications they post align with the measure specifications posted by CMS. We propose to revise § 414.1400(b)(4)(i)(B) to state that, for a QCDR measure, the entity must submit for CMS approval measure specifications including the Name/title of measure, National Quality Forum (NQF) number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the

QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. We request comments on this proposal. The burden estimates for the self-nomination process are currently associated with OMB Control No. 0938–1314 (CMS–10621). We refer readers to section V.B.9.c. of this rule for the associated burden estimates relevant to this proposal.

(c) QCDR Measure Approval Criteria

We refer readers to § 414.1400(b)(4)(iii), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 through 27595), the CY 2021 PFS final rule (85 FR 84937 through 84942), and the CY 2022 PFS final rule (86 FR 65540 through 65542) for previously finalized standards and criteria for QCDRs, specifically QCDR measure requirements.

We refer readers to the CY 2020 PFS final rule where we finalized requirements for QCDR measure testing (84 FR 63065 through 63067). Based on our goal that all measures available in MIPS are reliable and valid, we finalized in the CY 2020 PFS final rule a requirement for all QCDR measures to be fully developed and tested with complete testing results at the clinician level beginning with the CY 2021 performance period/2023 MIPS payment year (84 FR 63065 through 63067).[527] In consideration of the burden of collecting data as part of QCDR measure testing on clinicians and hospitals on the front lines of the COVID–19 pandemic, in the May 8th COVID–19 IFC and CY 2021 PFS final rule, we delayed the requirement for fully developed and tested QCDR measures by a year, to begin with the CY 2022 performance year (85 FR 27594 and 85 FR 84938 through 84939). Separately, to incorporate feedback from interested parties into the CY 2021 PFS final rule, we finalized an incremental approach to the QCDR measure testing requirements beginning with the CY 2022 performance year. Specifically, we finalized a policy that a QCDR measure must be face valid prior to being self-nominated for the CY 2022 performance year (85 FR 84939). For new QCDR measures to be approved, we must verify they are face valid for the initial performance year and fully tested for any subsequent performance year (85 FR 84939). Thus, a QCDR measure that we approve for the CY 2022 performance year; does not have to be fully tested until the CY 2023 performance year (85 FR 84939).

We recognize concerns expressed by interested parties regarding the burden of full measure testing and the continuing impact of the COVID–19 PHE (86 FR 65540 and 65541). Data collection efforts pose a challenge given the myriad disruptions to the health care system caused by the PHE, including clinicians' need to prioritize care for COVID–19 patients (and deprioritize data collection), and lost data due to the delay and cancelation of elective procedures. In particular, the COVID–19 extreme and uncontrollable circumstances exception decreased the number of groups reporting to MIPS through QCDRs. Without data from clinicians, QCDRs cannot complete their measure assessments, and delaying for one year will reduce the burden placed on QCDRs and clinicians. Despite these challenges, we believe QCDRs will soon be able to work with clinicians on full measure testing. Fully developed and tested measures improve measure reliability and validity thereby increasing clinician usability. Full measure testing also prevents instances where QCDRs may discover that a measure is not feasible part way through data collection (84 FR 63066). Therefore, we propose to revise our QCDR measure approval requirements again by delaying the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. Under this proposal, a QCDR measure approved for the CY 2023 performance year or earlier would not need to be fully developed and tested until the CY 2024 performance year. A new QCDR measure proposed for the CY 2024 performance year would be required to meet face validity. We would require full testing at the clinician level before the QCDR measure can continue in the program beyond the first year. We propose to amend § 414.1400(b)(4)(iii)(A)(*3*) to state that beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination. We request comments on this proposal.

(3) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77389), the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), and the CY 2022 PFS final rule (86 FR 65542 and 65550) for previously finalized policies for remedial action and termination of third party intermediaries.

We are proposing a few changes to the regulations relating to remedial actions and terminations set forth in § 414.1400(e). These include one revised and one new requirement for Corrective Action Plans (CAPs), and proposed termination of certain approved QCDRs and Qualified Registries that continue to fail to submit performance data.

Section 414.1400(e)(1) provides that, after providing written notice, CMS may take remedial action if CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised. As described in § 414.1400(e)(1)(i) and (ii), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP) and publicly disclosing an entity's data error rate on the CMS website until the data error rate falls below 3 percent.

As described in § 414.1400(e)(2), CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action; CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

We are taking this opportunity to propose a technical correction in § 414.1400(e)(3), to include the missing introductory text of, ''A data submission that,'' which we inadvertently failed to

[527] We refer readers to the Blueprint for the CMS Measures Management System for additional details and guidance on QCDR measure testing. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

include when finalizing our proposal to revise and redesignate existing language from former § 414.1400(f)(3)(ii) to paragraph (e)(3) in the CY 2022 PFS final rule (86 FR 65550). With this proposed technical correction, the provision at § 414.1400(e)(3) would read, ''A data submission that contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.''

(a) Revised Corrective Action Plan (CAP) Requirements

As described in § 414.1400(e)(1)(i), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP). As finalized in the CY 2021 PFS final rule and specified at §§ 414.1400(e)(1)(i)(A) through (D), unless different or additional information is specified by CMS, the CAP must address the following issues: (A) the issues that contributed to the non-compliance; (B) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (C) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future; and (D) a detailed timeline for achieving compliance with the applicable requirements.

In this proposed rule, we are proposing to revise the scope of affected parties impacted by the second CAP requirement at § 414.1400(e)(1)(i)(B). As finalized in the CY 2021 PFS final rule at § 414.1400(e)(1)(i)(B), we explained that, depending on the circumstances, non-compliance by a third party intermediary may affect an uncertain number of clinicians and groups and has the potential to implicate substantial program dollars. We noted our belief that the information regarding the scope of harms was necessary for the agency to assess the full program impact of the non-compliance, as well as our belief that it was important for the CAP to include this impact information regardless of the clinician's participation status, because non-compliance may have programmatic implications even if it does not affect payment, such as for data posted on the Physician Compare website (85 FR 84947).

We have become aware that in some cases, QCDRs granted licenses to the measures of another QCDR upon which a CAP has been imposed may be directly impacted by the issues that led to the CAP. We are proposing to broaden the scope of affected parties under the CAP requirement at § 414.1400(e)(1)(i)(B) to also identify impacts to any QCDRs that were granted licenses to the measures of the affected QCDR, rather than limit the identification of impacts to clinicians only. We are also proposing a technical correction in § 414.1400(e)(1)(i)(B) to correct the word ''voluntary'' to ''voluntarily.'' Accordingly, we propose to revise the CAP requirement at § 414.1400(e)(1)(i)(B) to require the third party intermediary to address in its CAP the impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

We also propose to add a new CAP requirement to require the third party intermediary to notify the parties identified in proposed § 414.1400(e)(1)(i)(B) of the impact to these parties by submitting a communication plan. The intent of this proposal is to enable affected parties to better understand and prepare for any operational and other challenges as needed. We believe having third party intermediaries submit a communication plan as part of their CAP would ensure third party intermediaries directly communicate the situation and its impact to these parties in a timely and consistent manner. Accordingly, we propose to add § 414.1400(e)(1)(i)(E) to require the third party intermediary to develop a communication plan for communicating the impact to the parties identified in proposed § 414.1400(e)(1)(i)(B). Specifically, as proposed above, this would include individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed. We refer readers to section V.B.9.c. of this rule for the associated burden estimates relevant to these proposals. We request comments on these proposals.

(b) Termination of Approved QCDRs and Qualified Registries That Have Not Submitted Performance Data

In the CY 2022 PFS final rule, we noted that we had identified a number of QCDRs and qualified registries that had continued to self-nominate to become a third party intermediary for the MIPS program but had not submitted clinician, group, or virtual group data to CMS (86 FR 65545). We further noted as the MIPS program continues to mature, we wished to reduce the number of vendors that self-nominate to become a qualified vendor but do not actively participate in the MIPS program (*Id.*). We also noted that our goal was to decrease the operational burden on CMS and those vendors that do not submit MIPS data to CMS (86 FR 65546). Accordingly, we finalized requirements for approved QCDRs and qualified registries that have not submitted performance data to submit a participation plan as part of their self-nomination process (*Id.*). We finalized an incremental approach to addressing this issue. First, we established a participation plan requirement, which requires a QCDR or qualified registry that was approved but did not submit data for any of the CY 2019 through 2023 MIPS payment years to submit a participation plan in order to be approved for the CY 2023 performance period/2025 MIPS payment year (§ 414.1400(b)(3)(vii)). Second, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan in order for it to be approved for the CY 2024 performance period/2026 MIPS payment year or for a future performance period/payment year (§ 414.1400(b)(3)(viii)).

Even with the participation requirements in place, we remain concerned about the administrative burden created by QCDRs and qualified registries that submit the required participation plans during the self-nomination process and continue as an approved QCDR or qualified registry, yet continue not to submit MIPS data to CMS. Maintaining these vendors that do not actively participate does not provide a benefit to the MIPS program, rather it creates confusion for interested parties by including these vendors in our qualified postings (86 FR 65545).

Our goal is also to decrease the operational burden on CMS and interested parties. CMS would decrease its operational burden by eliminating

the need to screen these entities. Removing QCDRs and qualified registries who do not actively participate from our qualified postings would also decrease the administrative burden for clinicians trying to identify an active participating QCDR or qualified registry.

Accordingly, beginning with the CY 2024 performance period, we propose to terminate those QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period. For example, if a QCDR or qualified registry is required to submit a participation plan during the self-nomination process for the CY 2024 performance period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for the CY 2022 and 2023 performance periods, and CMS approves their participation plan, but the QCDR or qualified registry continues to not submit MIPS data for the CY 2024 performance period (CY 2024 performance data is submitted by March 2025), then under our proposed policy, that QCDR or qualified registry would be terminated.

Specifically, we propose to add a new ground for termination at § 414.1400(e)(5) stating that, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under § 414.1400(b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under § 414.1400(b)(3)(viii), will be terminated. We refer readers to section V.B.9.c. of this rule for the associated burden estimates relevant to this proposal. We request comments on this proposal.

Finally, in conjunction with our proposal in section IV.A.10.g.(1)(b) above to amend the definition of ''third party intermediary'' to refer to subgroups and APM Entities, we are proposing a conforming change to § 414.1400(e)(2), which currently states that CMS may immediately or with advance notice terminate ''the ability of a third party intermediary to submit MIPS data on behalf of MIPS eligible clinician, group or virtual group'' under certain circumstances. Rather than amend this provision to add references to subgroups and APM Entities, we propose to revise § 414.1400(e)(2) by removing the previously quoted phrase. If this proposal is finalized, the revised regulation would simply provide that CMS may immediately or with advance notice ''terminate a third party intermediary'' under the specified circumstances. We request comments on this proposal.

(4) Auditing of Entities Submitting MIPS Data

(a) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77389 through 77390), we finalized that third party intermediaries submitting MIPS data must comply with auditing procedures as a condition of qualification and approval to participate in MIPS, including the requirement to make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data (§ 414.1400(f)(1)).

(b) Proposed Revisions to the Requirement to Make Contact Information Available

In conjunction with our proposal in section IV.A.10.g.(1)(b) above updating the definition of a third party intermediary, we are similarly proposing to revise the requirements codified at § 414.1400(f)(1) to account for third party intermediaries reporting on behalf of subgroups and APM Entities. Additionally, we are also proposing to update the requirement to apply to third party intermediaries submitting data on behalf of virtual groups. We therefore propose to update § 414.1400(f)(1) to require that the entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email. We invite public comment on this proposal.

(5) Requests for Information

(a) Request for Information on Third Party Intermediary Support of MVPs

In the 2022 PFS rule (86 FR 65394 through 65395) we discussed our proposals related to furthering our transition to MVPs. We believe it is important to allow third party intermediaries to support MVPs. Furthermore, we noted that we expect QCDRs, qualified registries, and Health IT vendors who support MVPs to support all measures and activities across the quality, Promoting Interoperability, and improvement activities performance categories that are included in the MVP (86 FR 65543). Thus, we believe it is important for third party intermediaries to have the capabilities to support MVPs (86 FR 65415 and 65542 through 65544).

Although our MVP proposals have generally been supported, some third party intermediaries have had questions and expressed concerns with the requirement for third party intermediaries to support all measures within an MVP due to operational limitations (86 FR 65543). While we recognize these limitations, we believe allowing third party intermediaries to only support specific measures in an MVP creates undue burden on the MVP Participant and limits the clinicians' choice of measures available.

Given public comments on the challenges of the current requirement to support all quality measures within an MVP (86 FR 65543), we are requesting input on the following:

- Should third party intermediaries have the flexibility to choose which measures they will support within an MVP?
- What are the barriers/burdens that third party intermediaries face to supporting all measures within an MVP?
- What type of technical educational resources would be helpful for QCDRs, qualified registries, and Health IT vendors to support all measures within an MVP?

We request comments on these questions.

(b) Request for Information on National Continuing Medical Education (CME) Accreditation Organizations Submitting Improvement Activities

We have signaled an interest in aligning MIPS with efforts clinicians undertake to maintain their state licensure and, as appropriate, board certification status, which often requires completion of Continuing Medical Education (CME) requirements and/or Maintenance of Certification (MOC) requirements. We are considering whether national continuing medical education (CME) accreditation organizations that provide certification of CME could serve as a new type of third party intermediary to submit data for clinicians seeking improvement activities performance category credit for IA_PSPA_28, ''Completion of an Accredited Safety or Quality Improvement Program,'' and IA_PSPA_2, ''Participation in MOC Part IV,'' which are both medium-weighted improvement activities, so that clinicians would not need to attest to completion of the improvement

activities through the QPP web portal. We are considering how to include information from national CME accreditation organizations in MIPS.

Currently, the only entities that are permitted to submit attestations on behalf of clinicians are third party intermediaries which includes QCDRs, qualified registries, health IT vendors, and CMS-approved survey vendors. We are considering approaches to including CME accreditation organizations as third party intermediaries, however our current third party intermediary policies do not allow third party intermediaries to submit data solely for the improvement activities performance category. We have established that QCDRs and quality registries must support the reporting of three performance categories: quality; Promoting Interoperability; and improvement activities (§ 414.1400(b)(1)(i). We have finalized requirements that Health IT vendors supporting MVPs must be able to submit data for the quality, Promoting Interoperability, and improvement activities performance categories (§ 414.1400(c)(1)(i)). In the quality performance category, QCDRs, quality registries and Health IT vendors are not required to support the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for MIPS surveys and qualified registries and Health IT vendors are not required to support QCDR measures (85 FR 84926). CMS-approved survey vendors are allowed to report the CAHPS for MIPS survey only for the quality performance category (§ 414.1400(d)).

We are considering establishing a different type of third party intermediary, that allows national CME accreditation organizations to submit improvement activities based on completion of CME or MOC for the improvement activities performance category. We are seeking comment on whether a new type of third party intermediary would be valuable to clinicians. We believe that if we add a new type of third party intermediary, we should consider only national CME accreditation organizations to reduce potential clinician confusion and program complexity. We realize there are numerous issues on which we need feedback to determine the usefulness of CME accreditation organizations reporting for clinicians and to fully implement policies. We are interested in the value to clinicians, including burden reduction, to allow CME accreditation organizations to submit one or two improvement activities. We are interested in the types of organizations that should be considered if we establish a different type of third party intermediary and seek feedback on criteria for selection. We also are interested in benefits and barriers to the CME accreditation organizations if we established a different type of third party intermediary. It is important to note that all requirements that apply to third party intermediaries would need to be applied to CME Accreditation Organizations. We would need to establish criteria for the types of CME accreditation organizations that would be included, a review process to evaluate vendor application forms, requirements for yearly vendor training and additional training as required, submission of a Quality Assurance Plan (QAP) regarding the data submitted, and policies about the public posting of information submitted.

We are seeking feedback on the value to clinicians of adding CME accreditation organizations as third party intermediaries including burden reduction, criteria for selecting CME accreditation organizations including the types of entities that should be considered and implementation policies.

(i) Request for Information on Value of Adding CME Accreditation Organizations as Third Party Intermediaries

We are requesting feedback on the value to clinicians of the program including CME accreditation organizations as a new type of third party intermediary that submits data on improvement activities that align with efforts clinicians undertake to complete CME, rather than attest to completing the activity at the time of submission.

- What is the value to clinicians for adding a new third party intermediary as an alternative method of data submission for the two improvement activities noted above, rather than attesting to completion of the improvement activities?
- What considerations are there for including a new type of third party intermediary that supports only select improvement activities in the improvement activities performance category? Currently, completion of the improvement activities related to CME and MOC do not satisfy the requirements of the improvement activities performance category; additional improvement activities must be submitted to meet the requirements. Improvement activities related to CME and MOC are not included in all MVPs. We are concerned that including an additional reporting method might be confusing for clinicians, who would need to attest to additional improvement activities to meet requirements of the improvement activities performance category. If a new type of third party intermediary was created that allowed a CME accreditation organization to submit data for select improvement activities, would there be any additional burden or operational costs to clinicians using multiple vendors to submit data to meet the requirements of the improvement activities performance category?
- If a new type of third party intermediary was created for reporting only the improvement activities performance category, are CME accreditation organizations interested in developing capacity over time to submit additional improvement activities in the Improvement Activities Inventory, especially activities that address CMS priority issues, such as closing the health equity gap, inclusion of the patient voice in quality improvement, shared decision-making, and care coordination?
- As the program transitions to MVPs, we are interested in reducing complexity and burden for clinicians. Would CME accreditation organizations need to be able to support MVPs (submission of measures and activities for quality, Promoting Interoperability and improvement activities performance categories) to reduce burden?
- Are there other approaches to aligning MIPS and MVP requirements with completion of CME requirements and/or MOC requirements that we should consider?

(ii) Request for Information on Criteria for Selecting the CME Accreditation Organizations

We request feedback on the types of organizations that should be considered for this potential new type of third party intermediary.

- If we add a new type of third party intermediary, we believe we should develop criteria that permit only national CME accreditation organizations to become a new third party intermediary, to reduce confusion and complexity for clinicians. Are there special considerations or factors we should consider in the criteria related to regional CME accreditation organizations?
- If we develop a new type of third party intermediary that allows only reporting for specific improvement activities for the improvement activities performance category, what type of selection criteria should be established? What type of entity would be eligible to be this new third party intermediary type? For example, would only national certifying accrediting organizations for CME with the ability to report for all

MIPS clinicians meet the requirement when we initially implement the policy because the relevant improvement activity is specific to physicians: IA_PSPA_28, ''Completion of an Accredited Safety or Quality Improvement Program'' and IA_PSPA_2, ''Participation in MOC Part IV''? Should we consider only organizations that can support submission of all improvement activities in the improvement activities performance category to reduce clinician confusion and burden?

- Should we allow only CME accreditation organizations that can submit all measures and activities required in MVPs, to parallel the requirements for QCDRs, qualified registries and Health IT vendors? Are there technical resources that would be helpful to CME accreditation organizations to describe how measures and activities are submitted to CMS to assist a transition to supporting three performance categories? If CME accreditation organizations could support measures and activities in MVPs, would we need to develop any separate third party intermediary policies for the selection and approval of national CME accreditation organizations?
- Should we consider inclusion of organizations that are accredited to provide continuing clinicians education (for example, CME, certified nurse educator (CNE), etc.)?
- Should we consider organizations that accredit facilities and clinical practices as part of this new third party intermediaries type?

(iii) Request for Information on Third Party Intermediary Implementation Policies

We request feedback on how third party intermediary policies should be maintained or modified if we add a new type of third party intermediary.

- If we develop a new type of third party intermediary, we believe we should align with existing third party intermediary requirements and policies to the extent possible. Are there concerns with current policies used for CMS-approved vendors that includes completion of a vendor application form; completion of yearly vendor training and additional training as required; submission of a QAP; and the requirement that CMS be able to publicly post submitted data? Are there recommendations about this approval process?
- Third party intermediaries currently submit data via a file upload or application programming interface or API submission. Should we maintain submission requirements? Are there advantages or concerns with allowing the direct, log in and upload, and attestation submission types? Would any other submission types or methodologies be needed to submit improvement activity data for this new third party intermediary type?

We request feedback on these topics.

h. Public Reporting on the Compare Tools Hosted by HHS

Section 10331(a)(1) of the Affordable Care Act authorized the development of a Physician Compare internet website with information on physicians and other eligible professionals enrolled in Medicare who participate in the Physician Quality Reporting Initiative (PQRI). Section 1848(q)(9) of the Act, as added by section 101(b) of MACRA, aligned Physician Compare with the newly-established Merit-Based Incentive Program by requiring the public reporting of MIPS performance information for MIPS eligible professionals through Physician Compare.

For previous discussions on public reporting, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2022 PFS final rule (86 FR 65550 through 65554) and the Care Compare: Doctors and Clinicians Initiative Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC.* We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as ''compare tool'' throughout this proposed rule (86 FR 39466).

(1) Telehealth Indicator

Prior to the start of the COVID–19 public health emergency (PHE) in March 2020, Medicare paid for telehealth under limited circumstances, with telemedicine services restricted to rural or health professional shortage areas, established patients, or certain types of health care providers. In response to the ongoing PHE, we expanded Medicare payment for telemedicine services to increase access to care. In the CY 2021 PFS final rule, we finalized a number of more permanent Category 1 CPT codes and authorized a number of time-limited Category 3 codes due to the PHE (85 FR 84502 through 84540). Additionally, in the CY 2022 PFS final rule, we expanded upon definitions of different telehealth services to increase coverage, and extended the time period for certain Category 3 codes (86 FR 65047 through 65065).

According to the September 2021 Medicare Telemedicine Snapshot,[528] telehealth services have increased more than 30-fold since the start of the PHE and have been utilized by more than half of the Medicare population. With the increase in patients seeking telehealth due to the ongoing PHE and CMS finalizing and expanding coverage of certain Category 1 and Category 3 telehealth services codes, adding an indicator to clinician and group profile pages would clarify for website users which clinicians offer telehealth services.

The Compare tool includes information on how beneficiaries may access care. We believe knowing whether a clinician offers services via telehealth would be useful to patients and caregivers generally, beyond the PHE, particularly for those who have access to care barriers such as living in rural areas or have transportation constraints. The ability to search for clinicians and groups who offer telehealth would also eliminate the burden of patients and caregivers having to call offices to obtain this information.

Our research suggests that the addition of a telehealth indicator would meet a gap in the current information we provide on access to care and that such an indicator would be well understood by users. Keyword searches from the legacy Physician Compare website showed that, historically, website users search for telehealth information. Additionally, user testing we conducted with Medicare beneficiaries and caregivers showed that users accurately understood the meaning of a telehealth indicator and some even expressed an interest in knowing which services, specifically, might be offered via telehealth. Most users found the telehealth indicator to be important and useful when selecting a clinician. Users also mentioned convenience or personal preference as

[528] CMS, *Medicare Telemedicine Snapshot: March 2020–Feb. 2021* (2021), *https://www.cms.gov/files/document/medicare-telemedicine-snapshot.pdf. See also Medicare Telemedicine Snapshot Data File, https://www.cms.gov/files/zip/medicare-telemedicine-snapshot-data-file.zip.*

reasons a telehealth indicator would be important to include on the website.

We also believe that publicly reporting a telehealth indicator on clinician and group profile pages would further CMS's health equity goals. According to the aforementioned Medicare Telemedicine Snapshot, more than half of the Medicare population in almost every racial/ethnic group regardless of sex or Medicare and Medicaid status are utilizing telehealth services. Given the exponential increase in Medicare telehealth usage by Medicare users over the past 2 years, particularly by those in areas with limited healthcare access, and those who cannot physically access a clinician's office, publicly reporting information on which clinicians furnish services via telehealth would aid in more widely applicable health care provider selection across the Medicare and dually eligible Medicare and Medicaid populations, since some beneficiaries have preferences for, or limitations preventing them from-seeing a clinician in-person. For these reasons, we propose adding a telehealth indicator to clinician and group profile pages, as technically feasible. Along with the indicator, we would include a statement on the profile page caveating, in a user-friendly way based on consumer testing, that the clinician or group only provides some, not all, services via telehealth.

To develop the indicator that would display on the Compare tool clinician and group profile pages, we propose to identify clinicians who perform telehealth services using Place of Service Code 02 (indicating telehealth) on paid physician & ancillary service (that is, carrier) claims, or modifier 95 appended on paid claims. To keep the indicator current and address concerns that some telehealth codes are time-limited, we would use a 6-month lookback period and refresh the telehealth indicator on clinician profile pages bi-monthly, which is the same cadence in which we update other clinician directory information. Frequently updating the telehealth indicator information would ensure that when a time-limited Category 3 codes expires, a clinician who only bills telehealth services under that code would no longer have a telehealth indicator on their profile page.

We seek comment on all aspects of our proposals to add a telehealth indicator to clinician and group profile pages, as technically feasible; our proposed approach to identifying clinicians and groups furnishing telehealth services; and our proposed 6-month lookback period and bi-monthly data refresh frequency, which account for potential changes to telehealth coverage.

(2) Publicly Reporting Utilization Data on Profile Pages

Section 104(a) of MACRA provides that, beginning with 2015, the Secretary shall make publicly available on an annual basis, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals, on items and services furnished to Medicare beneficiaries. The information made available must be similar to the physician and other supplier utilization data we have historically made available and shall include information on the number of services furnished by the physician or other eligible professional under Medicare, which may include information on the most frequent services furnished or groupings of services. Section 104(e) of MACRA requires that we integrate this data into the Compare tool.

To satisfy section 104(e), we implemented a policy of including utilization data in a downloadable format from late 2017 using the most currently available data and that the specific codes to be included were determined using data analysis and reported at the eligible clinician level (80 FR 71130). We also finalized a policy of continuing to include utilization data in the downloadable database (81 FR 77398). This information continues to be available today in the Medicare Provider Data Catalog (PDC) available at *https://data.cms.gov/provider-data/topics/doctors-clinicians.* Separately, we have reported on the Compare tool clinician training information as well as a clinician's primary and secondary specialties.[529]

We believe it would be useful to patients and their caregivers, when making healthcare decisions, if a subset of procedures performed were publicly reported on clinician profile pages in an understandable and meaningful way. To date, we have gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the public use file (PUF) file entitled ''Physician and Other Supplier Data.'' These data are useful to the healthcare industry, healthcare researchers, and other interested parties who have the expertise to accurately interpret these data and use them in meaningful analyses. However, this information is presented in a technical manner that is not easily accessible or usable by patients, who do not frequently visit *data.cms.gov* or understand medical procedure coding. Additionally, the amount of information available in the PUF may overwhelm patients and caregivers.

We envision that reporting utilization data on patient-facing clinician profile pages would provide two main areas of benefit. The first would be to allow for more granular clinician searches. Patients would not only be able to find specific types of clinicians but also those clinicians who have performed specific types of procedures. The second would be to provide categories of utilization data in a plain language display that is more usable to patients and their caregivers than what is available in the PDC.

For example, someone with severe arthritis of the knee may want to search for an orthopedic surgeon who specifically performs knee replacements. Currently, the clinician search returns only results for ''orthopedic surgeons'' generally. That is, the patient does not see which clinicians have performed knee replacements in the past, and the patient likely would need to spend time calling clinicians to ascertain such information. We believe that indicating which clinicians have performed certain procedures would relieve some of this patient burden as it would yield more specific and useful search results.

In order to publicly report procedural utilization data in a meaningful way to patients and caregivers, rather than showing thousands of rows of individual Healthcare Common Procedure Coding System (HCPCS) data, as we do for the research community in the PDC, we propose to collapse HCPCS codes using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System into procedural categories. BETOS is a taxonomy that allows for the grouping of health care services codes for Medicare Part B into clinically meaningful categories and subcategories. Additional BETOS information is available at *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system.* For example, applying categories would enable us to list that a clinician performs knee arthroplasties, which we could further simplify to knee replacements for understandability instead listing each of nine unique procedure codes indicating

[529] CMS, *Physician Compare Report to Congress* 36 (2014), available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Downloads/Physician-Compare-Report-to-Congress.pdf.*

the specifics of exactly which bones and implants were utilized. We would exclude non-specific procedure codes, such as evaluation and management (E&M) codes for office visits which do not provide context about the care provided, and low complexity procedures such as basic wound care or administering a vaccine because these codes encompass many types of care and are not specific enough about the services covered. For procedures in which no Restructured BETOS categories are available, we would utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures.

Prior to publishing this data, we would conduct user testing with patients and caregivers to determine which procedures are of most importance, as well as how to best display and plain language utilization data on profile pages. User testing would also inform the appropriate context necessary to display utilization data in a meaningful way that ensures it is interpreted accurately.

We note that the utilization data shown on profile pages would only reflect Medicare claims data. Though this would provide information to patients and caregivers about which procedures are covered by Medicare, the utilization data would not include procedures performed for patients who have other types of insurance. For this reason, we would include a disclaimer on profile pages that the utilization data only represents the care that has been provided to Medicare beneficiaries and does not include those of patients with other forms of insurance.

In summary, we believe that publicly reporting summary utilization data on profile pages in a way that is easily accessible and understandable by patients and caregivers will assist in more informed healthcare decision-making and further the implementation of the MACRA requirement to publicly report utilization data beyond what we publish today in the PDC. It would allow patients and their caregivers to more easily find and compare clinicians who perform specific procedures without having to contact each individual clinician directly.

Therefore, we propose publicly reporting Medicare procedural utilization data on the Compare tool clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions. We would begin publicly reporting procedural utilization data no earlier than CY 2023. We will use a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. We seek comment on all aspects of this proposal, including the proposed approaches to identifying the most relevant and understandable procedural categories.

(3) Incorporating Health Equity Into Public Reporting Request for Information

In an effort to gather information from interested parties to help guide efforts to advance health equity, we seek comment on ways to incorporate health equity into public reporting on doctor and clinician profile pages with the goal of ensuring that all patients and caregivers can easily access meaningful information to assist with their healthcare decisions. As defined by CMS, for the purpose of this request for information, health equity means ''the attainment of the highest level of health of all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [530] In accordance with this definition and other CMS efforts to improve health equity, we believe that empowering all patients with information that enables them to select high quality, high value clinicians will be one facet that helps improve outcomes and close disparity gaps across social risk factors, race, and ethnicity.

We note that, consistent with § 414.1395(b) and subject to the limitations of § 414.1395 (c), all new MIPS quality or cost measures, improvement activities, and Promoting Interoperability measures and attestations, including those that aim to improve health equity will be available for public reporting on the Compare tool. CMS's public reporting of such information would provide patients and caregivers with information regarding health equity efforts and culture within a particular practice. For example, should the proposed improvement activity ''Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients'' be added to the improvement activity inventory, visitors to the Compare tool could see, when selecting a clinician, which clinicians chose to complete this improvement activity. This may be especially meaningful for patients concerned about care for LGBTQ+ individuals when selecting a clinician.

We have also considered including additional information to the Compare tool clinician and group profile pages, such as whether the clinician or group has language services available, speaks other languages besides English, and whether they accept insurance outside of traditional Medicare Fee-for-Service, such as Medicaid, Medigap, Medicare Advantage, and other commercial insurance. During prior user testing sessions, participants have indicated an interest in seeing more demographic information on profile pages including available language services, other languages spoken, and additional insurances accepted. Beneficiary inquiries from the 1–800–MEDICARE have also shown that patients are interested in information about available language services provided by a clinician's office.

However, we lack data sources from which to obtain language services, languages spoken, and other payer information. That said, we request information on what additional information, such as the information described previously in this section of the proposed rule, should be publicly reported on the Compare tool, as well as what readily available, centralized data sources could be used for gathering them. Additionally, we request information on other ways to incorporate health equity into public reporting. Specifically, we request information on the following questions:

- Should we publicly report available language (including sign language) services on a clinician's Compare tool profile pages? If so, what data sources are available? This could also include if a clinician offers translator services including human interpreters, digital interpreter, and languages the clinician or staff speak.
- Should we publicly report information through the Compare tool on whether clinicians and groups accept other insurance outside of traditional Medicare Fee-for-Service, such as Medigap, and Medicare Advantage; Medicaid; and commercial insurance for non-Medicare eligible patients, including through the healthcare exchanges. If so, what data sources are available for this information?
- What additional information would be useful to add to Compare tool profile pages to help patients and caregivers make healthcare decisions?

11. Overview of the APM Incentive

a. Overview

Under the Quality Payment Program, an eligible clinician who is a Qualifying

[530] *https://www.cms.gov/pillar/health-equity.*

APM Participant (QP) for a performance year earns an APM Incentive Payment, which is made in the corresponding payment year for payment years 2019 through 2024. As provided in our regulation at § 414.1450(d), this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2022 APM Incentive Payment will correspond to the 2020 performance year), and at § 414.1450(b)(1) the APM Incentive Payment is equal to 5 percent of the eligible clinician's estimated aggregate payments for covered professional services in the base period (the year between the QP performance and payment years).

b. APM Incentive Payment Recipient

In the CY 2017 Quality Payment Program final rule (81 FR 77008, 77487), we initially finalized a policy that the APM Incentive Payment is made to the TIN associated with the APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. In the CY 2021 PFS final rule (85 FR 84472, 84949 through 84950), we revised our approach to identifying the TIN or TINs to which we make the APM Incentive Payment at § 414.1450(c) to use a stepwise hierarchy to identify an appropriate payee TIN or TINs.

c. Public Notice

As specified in § 414.1450(c)(8), we notify QPs for whom we are unable to identify an appropriate TIN to which to make the APM Incentive Payment through a notice published annually in the **Federal Register**. In that notice, we include information on how the QP can update their information to enable CMS to make the APM Incentive Payment. Under our current policy, the deadline for providing CMS with updated information is the later of November 1 of each payment year or 60 days from the date on which we make the initial round of APM Incentive Payments for such year.

Section 414.1450(d) specifies that we make APM Incentive Payments as soon as practicable following calculation and validation of the APM Incentive Payment amount, but in no event later than 1 year after the incentive payment base period, defined in § 414.1305 as the calendar year prior to the year in which CMS disburses the APM Incentive Payment. Based on our experience and lessons learned in disbursing APM Incentive Payments, we have determined that the November 1 cutoff date for QPs to provide us with updated information does not leave sufficient time for us to process the information provided and make payments within the timeframe established in § 414.1450(d). In addition, we made operational adjustments beginning in the 2021 payment year that allowed us to make the initial round of APM Incentive Payments earlier in the calendar year than was possible in the first 2 payment years. Because we are now able to notify QPs for whom we have not identified a TIN to which to make the APM Incentive Payment through the **Federal Register** notice earlier in the payment year, and because we have found that we need additional time to process the updated information we receive in response to the notice, we now are proposing to change the specified cutoff date from November 1 to September 1 of the payment year, or 60 days from the date on which we make the initial round of payments, whichever is later. As is the case under the current policy, after the specified cutoff date, we will no longer accept updated information from QPs or their representatives, and any claims to an APM Incentive Payment for such QPs for the payment year will be forfeited.

We believe this change to the cutoff date for response to the public notice would allow us to disburse APM Incentive Payments more efficiently and effectively, reducing the time within which we make the remaining APM Incentive Payments for the payment year. This change would also improve our ability to make all APM Incentive Payments within the timeframe established under § 414.1450(d), and therefore, affected QPs would not have to wait as long to receive their payments.

We seek comment on this proposal to amend § 414.1450(c)(8) to change the cutoff date for response to the public notice from November 1 to September 1 of each payment year, or 60 days from the date on which we make the initial round of APM Incentive Payments, whichever is later.

d. Request for Information on Quality Payment Program Incentives Beginning in Performance Year 2023

Section 1833(z)(1) of the Act provides for APM Incentive Payments in each year for eligible clinicians who are QPs with respect to a year from 2019 through 2024. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is a QP for such year, there is an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year. Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act.

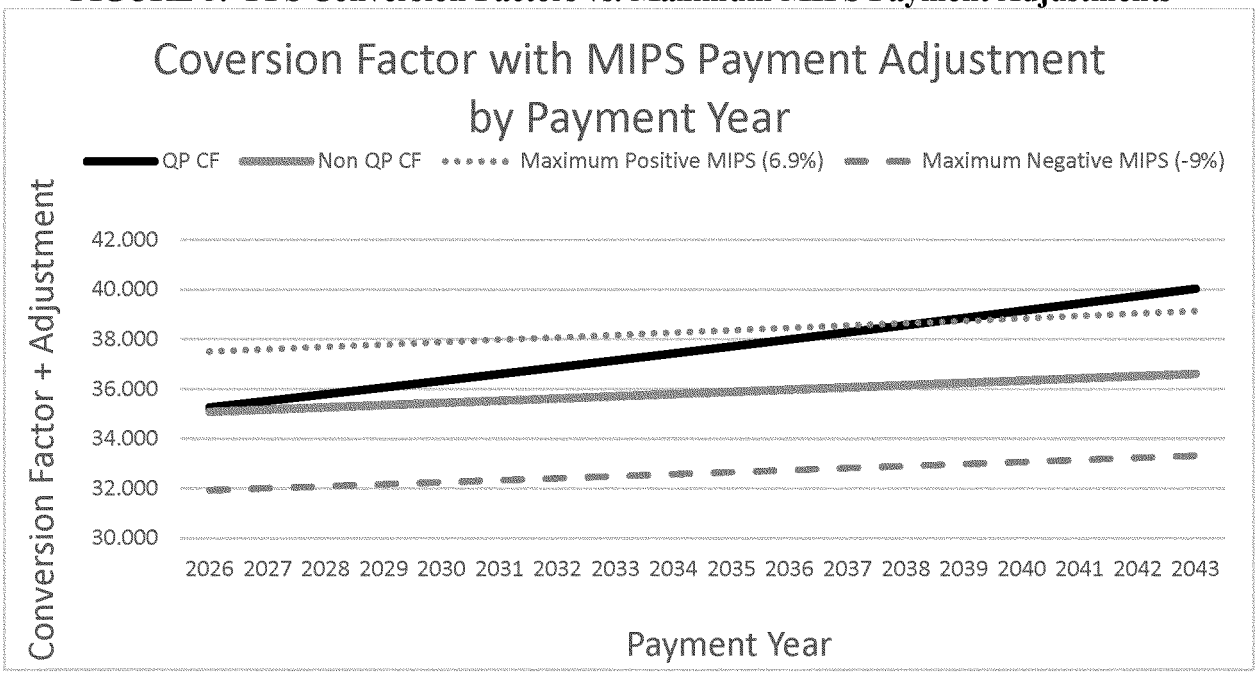
In the CY 2017 Quality Payment Program final rule (81 FR 77445), we established a policy that, beginning with the 2017 QP Performance Period, the QP Performance Period would be the calendar year that is 2 calendar years before the payment year for the APM Incentive Payment. Thus, we established that the first QP Performance Period would begin on January 1, 2017, the first ''base year'' (established at 81 FR 77481 and 77482) for which we would use claims for professional services to calculate the 5 percent APM Incentive Payment amount would be in 2018, and the first payment year for the APM Incentive Payment would be in 2019 as required by the statute. The QP Performance Period, base year, and payment year continue in this fashion through payment year 2024, which is the final year for which the statute authorizes an APM Incentive Payment.

After performance year 2022, which correlates with payment year 2024, there is no further statutory authority for a 5 percent APM Incentive Payment for eligible clinicians who become QPs for a year. In performance year 2023, which correlates with payment year 2025, the statute does not provide for any type of incentive for eligible clinicians who become QPs. Beginning with performance year 2024, which correlates with payment year 2026, section 1848(d)(1) of the Act provides for the application of two different PFS conversion factors depending on whether the services are furnished by an eligible clinician who is a QP for the year. The PFS conversion factor is the fixed-dollar constant, updated each year in accordance with statute, that is used to convert the RVUs (relative value units) for a service, after application of geographic practice cost indices to adjust for cost variations, into PFS payment amounts. Section 1848(d)(20) of the Act specifies that, beginning in CY 2026 (which is the payment year that correlates with the 2024 QP Performance Period under the Quality Payment Program), the update to the

''qualifying APM conversion factor'' (hereafter, ''QP conversion factor'') that applies for eligible clinicians who are QPs with respect to the payment year is 0.75 percent, and the update to the ''non-qualifying APM conversion factor'' (hereafter, ''general conversion factor'') that applies for eligible clinicians who are not QPs with respect to the year (as well as other types of suppliers that are not eligible clinicians under the Quality Payment Program) is 0.25 percent. With the differentially higher 0.75 percent update to the QP conversion factor compounding each year beginning with CY 2026, compared to the 0.25 percent update to the general conversion factor in each year, the two PFS conversion factors will continue to diverge with each year, as illustrated in the chart below

Beginning in payment year 2025, the statutory incentive structure under the Quality Payment Program for eligible clinicians who participate in Advanced APMs stands in contrast to the incentives for MIPS eligible clinicians. Specifically, as described in section VI.E.16.d.(4) of this proposed rule, we anticipate that the maximum potential positive payment adjustment that could be applied under MIPS for payment years beginning in 2025 will be at or above 6.9 percent, and the corresponding maximum negative payment adjustment will be 9 percent. While only some MIPS eligible clinicians could earn the maximum positive payment adjustment, there is nonetheless a significant range of potential positive payment adjustments under MIPS that would exceed the differentially higher QP conversion factor beginning in payment year 2026 and for many years to come. As illustrated in Figure 5, the QP conversion factor, with the compounded differentially higher 0.75 percent update in each year, is not expected to equate to the anticipated maximum available positive payment adjustment under MIPS until after CY 2038.

FIGURE 5: PFS Conversion Factors vs. Maximum MIPS Payment Adjustments*



*This graph depicts the PFS conversion factors that would apply for each year given the annual updates as specified in current statute, and does not otherwise depict an estimate of PFS payment rates for future years.

We note again that the statute does not provide for any financial incentives for eligible clinicians who achieve QP status in QP Performance Period 2023/payment year 2025. Because section 1848(q)(1)(C)(ii)(I) of the Act explicitly excludes eligible clinicians who are QPs for a year from being considered as MIPS eligible clinicians, eligible clinicians who are QPs for a year are not subject to MIPS for that year, and thus, cannot receive MIPS payment adjustments. As such, eligible clinicians who are determined to be QPs in performance year 2023 will be paid under the PFS in payment year 2025 at the same rate as any other eligible clinicians who are not subject to MIPS and suppliers that are not subject to the Quality Payment Program at all.

We recognize that the lack of any available financial incentive under the Quality Payment Program for QPs for the 2025 payment year could affect the willingness of some eligible clinicians to participate in Advanced APMs in performance year 2023. Moreover, we recognize that the substantial difference between the QP conversion factor that will apply for QPs beginning in CY 2026 and maximum positive payment adjustment available under MIPS might affect the willingness of eligible clinicians to participate in Advanced APMs for several years to come. We recognize that there are other factors that affect an eligible clinician's decision whether to participate in an Advanced APM, including the avoidance of MIPS reporting requirements and the availability of shared savings and other incentives within the various Advanced APMs.

However, we are concerned that the statutory incentive structure under the Quality Payment Program beginning in the 2023 performance year and corresponding 2025 payment year could potentially lead to a drop in Advanced APM participation, and a corresponding increase in MIPS participation as eligible clinicians may believe their payments would be higher if they receive the MIPS payment adjustment.

While it has been CMS's goal to increase MIPS participation, we continue to believe MIPS should be a first step on a glide path towards Advanced APM participation. Furthermore, we are concerned that a significant reduction in Advanced APM participation stemming from changes in financial incentives under the Quality Payment Program could potentially bias the CMS Innovation Center's model tests of voluntary Advanced APMs by leading clinicians who have performed well in Advanced APMs on both cost and quality metrics, to leave participation in the Advanced APM in which they currently participate, or decide not to apply for and participate in Advanced APMs, thereby interfering with the evaluation of current model tests and interfering with potential participation in future models.

We also are concerned that a shift of eligible clinicians into MIPS and out of Advanced APMs would be likely to affect the availability and distribution of funds in the budget-neutral MIPS payment pool. The average MIPS final score for MIPS eligible clinicians who were participants in MIPS APMs in 2020 was 96.24 points while the average MIPS final score for all other MIPS eligible clinicians was 84.42 points. Given these statistics, we can reasonably anticipate that eligible clinicians who would shift away from participation in Advanced APMs and into MIPS would increase the relative number of high-performing MIPS eligible clinicians likely to earn a positive MIPS payment adjustment. As a result of more MIPS eligible clinicians earning a positive MIPS payment adjustment, we would expect to see a corresponding reduction in the average and maximum positive MIPS payment adjustment due to the statutory requirement under section 1848(q)(6)(F)(ii) of the Act to maintain budget neutrality in MIPS.

We have considered a range of potential administrative actions within our authority that might address these concerns. For example, we explored options for modifying the Advanced APM criteria or the requirements for current and future Advanced APMs to permit some degree of flexibility for eligible clinicians to choose whether to be considered under either the MIPS or the Advanced APM track of the Quality Payment Program. We have found it difficult to conceive of potential administrative options that would increase flexibility for eligible clinicians without drastically modifying characteristics of Advanced APMs, including CEHRT use, quality-based payment, and financial risk. After further consideration, we have concluded that it would be more prudent to forego administrative action for the 2023 performance period and 2025 payment year, and instead to seek robust public input that we will consider in identifying potential options for the 2024 performance period and 2026 payment year of the Quality Payment Program (and potentially beyond). Specifically, we seek public comment on whether administrative action is needed beginning in the 2024 performance period and 2026 payment year, and if so, what would be the best approach to address the multi-faceted issues that arise with the end of statutory authority for an APM Incentive Payment for QPs and the transition to the differential QP and general conversion factors beginning in payment year 2026, which correlates to the 2024 performance year.

Taking into account that the current statute: (1) requires us to make QP determinations for eligible clinicians participating in Advanced APMs; (2) defines Advanced APMs as those APMs that require CEHRT use, sets payment based on MIPS-comparable quality measures, and assumption of more than nominal financial risk, as described at § 414.1415; and (3) specifically excludes QPs from being MIPS eligible clinicians, we are seeking input on what, if any, administrative actions eligible clinicians and APM Entities would potentially find helpful to better balance the payment incentives within the Quality Payment Program going forward, while continuing to encourage eligible clinicians and APM Entities to participate in APMs that align with the broader goals of CMS.

We are particularly interested in receiving public comments in response to the questions stated below, which will help us to gauge options going forward. We are also considering holding a public listening session in the near future to gather additional feedback on these questions and ideas, though we encourage the public to submit written comments on this Request for Information.

- What are your primary considerations going forward as you choose whether to participate in an Advanced APM or be subject to MIPS reporting requirements and payment adjustments? What factors are the most important as you make this decision?
- If you are participating in an Advanced APM now and have been or could be a QP for a year, will the end of the 5 percent lump-sum APM Incentive Payments beginning in the 2025 payment year (associated with the 2023 QP Performance Period) cause you to consider dropping your participation in the Advanced APM, which would mean forgoing QP determinations, thereby ensuring you are subject to MIPS reporting requirements and payment adjustments?
- Going forward, attaining QP status for a year through sufficient participation in one or more Advanced APMs will enable an eligible clinician to, for a year: (1) continue receiving any financial incentive payments available under the Advanced APM(s) in which they participate, subject to the terms and conditions applicable to the specific Advanced APM(s); (2) be paid under the PFS in the payment year using the a higher QP conversion factor (0.75 percent rather than 0.25 percent) beginning in payment year 2026; and (3) not be subject to MIPS reporting requirements or payment adjustments. Do these three conditions provide sufficient incentives for you to participate in an Advanced APM, or would you instead decide to be subject to MIPS reporting requirements and payment adjustments?
- Are there other advantages of MIPS participation that might lead a clinician to prefer MIPS over participation in an Advanced APM, such as: (1) quality measurement that may be specific to a particular practice area or specialty area; or (2) the desire for more precise accountability through public reporting of quality measure performance in the future?

e. Advanced APMs

(1) Advanced APM Criteria

(a) General Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

In this section of the proposed rule, we address policies regarding several aspects of the Advanced APM criteria. We provide a clarification around

payment based on quality measures and a proposal to modify the period of applicability for the generally applicable nominal amount standard.

(b) Payment Based on Quality Measures

In the CY 2017 Quality Payment Program final rule, we finalized the requirement for Advanced APMs that payment be based on quality measures at § 414.1415(b). In the CY 2019 PFS final rule (83 FR 59915 through 59938), we revised § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid. We also revised the requirement at § 414.1415(b)(3) that the quality measures upon which an Advanced APM bases payment must include at least one outcome measure (unless there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period) to provide, effective January 1, 2020, that at least one such outcome measure must either be finalized on the MIPS final list of measures as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

It has come to our attention that it may not be clear whether the two criteria at § 414.1415(b) require different quality measures. That is, interested parties have questioned whether two separate measures are required with one to meet each criterion, or whether it is sufficient that a single quality measure meets both of the criteria. Therefore, in this proposed rule, we propose to revise the regulation at § 414.1415(b)(3) and adding a new paragraph (b)(4) to clarify that the requirement for Advanced APMs that payment must be based on quality measures as specified at § 414.1415(b)(1) can be met through the use of a single quality measure that meets the criteria under both § 414.1415(b)(2) and (b)(3). Likewise, consistent with our practice of aligning Advanced APM and Other Payer Advanced APM policies to the extent feasible and appropriate, we are also proposing to revise § 414.1420(c)(3)(ii) and add a new paragraph (c)(4) to clarify that the requirement for Other Payer Advanced APMs that payment must be based on quality measures as specified at § 414.1420(c)(1) can be met through the use of a single quality measure that meets the criteria at § 414.1420(c)(2) and (c)(3). We seek public comment on these proposals.

(c) Generally Applicable Nominal Amount Standard

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on setting the revenue-based standard: (1) for 2019 and later at up to 15 percent of revenue; or (2) at 10 percent so long as risk is equal to at least 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1415(c)(3)(i)(A) our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods. We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we would address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

In the CY 2019 PFS final rule (83 FR 59922 through 59923), we revised § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

At the same time, we established the generally applicable revenue-based nominal amount standard for Other Payer Advanced APMs at § 414.1420(d)(3)(i) to reflect the same 8 percent standard for QP Performance Periods for years 2021 through 2024, but based on the total combined revenues from the payer to providers and other entities under the payment arrangement.

We are proposing to amend § 414.1415(c)(3)(i)(A) to permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the QP Performance Period. We are proposing this change because the nominal amount standard of 8 percent has worked well and we are making the change permanent at this time to provide continuity in policy into the future.

We are also proposing to amend § 414.1420(d)(3)(i) to permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement, consistent with our longstanding practice of aligning Advanced APM policies with Other Payer Advanced APM policies to the extent feasible and appropriate. We propose to amend these regulations to remove the specified end date of the 2024 QP Performance Period, such that the 8 percent standard would apply for all future performance years beginning with the 2023 QP Performance Period. This proposal would not change the current generally applicable revenue-based nominal amount standard. While we will continue to evaluate the generally applicable revenue-based nominal amount standard going forward and may determine at some point that it would be appropriate to propose to change the generally applicable revenue-based nominal amount standard, we believe that the current standard of 8 percent continues to be appropriate at this time for both the Advanced APM and Other Payer Advanced APM financial risk criteria.

We seek public comment on the proposals to amend § 414.1415(c)(3)(i)(A) and 414.1420(d)(3)(i) to make permanent the 8 percent level of the generally applicable revenue-based nominal amount standard such that it would apply to all future QP Performance Periods beginning January 1, 2023.

(d) Medical Home Model 50 Eligible Clinician Limit

In the 2017 Quality Payment Program final rule (81 FR 77428), we finalized a policy for the Medical Home Model nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates in an Advanced APM through a Medical Home Model.

At that time, we described the way in which we would identify APM Entities that meet this standard as looking for ''APM Entities that participate in Medical Home Models and that have 50 or fewer eligible clinicians in the organization through which the entity is owned and operated.'' We defined organizational size as measured based on the size of the ''parent organization'' rather than the size of the APM Entity itself. We recognized that there would

be ''additional but [. . .] achievable'' burden to correctly identify parent organizations and their size (81 FR 77428).

In the 2017 Quality Payment Program final rule, we responded to the many comments we had received in opposition to the proposal (81 FR 77429), where commenters expressed opinions that identifying eligible entities in this way was arbitrary, or that it would unfairly discriminate between similarly situated organizations. We finalized the proposal despite these concerns because we believed we could identify organizations that were or were not reasonably capable of taking on the generally applicable level of financial risk by identifying the ultimate size of the parent organization, and in so doing, identify organizations that should be excluded from the Medical Home Model financial risk standard.

After several years of implementation and upon closer analysis of our results under the Medical Home Model standard, we have gained experience about the composition of parent organizations and that there is a wide variation in how practices are organized and are proposing a change in our policy. These changes are based on a re-evaluation of two assumptions we used in finalizing the 50 eligible clinician limit, codified at § 414.1415(c)(7), have not borne out in practice.

Our belief that we could easily gather accurate data about the size and composition of ''parent organizations'' through disclosures from the APM Entities affiliated with them was misplaced. To accurately understand the numerous and varied ways in which a parent organization (itself a complex concept) may enter into contractual relationships with other subsidiary entities that have Taxpayer Identification Numbers (TINs), which otherwise might have no apparent relationship with one another, would require insight and access to private contracts do not have. The administration of QPP is not the same as the administration of an individual APM and we are not party to the contracts between those private entities. Based on the information about these relationships, we are unable to confidently say that, under the parent organization approach we had finalized, all similarly situated organizations are being treated in the same manner. On the other hand, we believe we have a good understanding of APM Entities and how they will manage financial risk from our time implementing the QPP and various APMs.

Based on this insight and experience implementing the 50 eligible clinician limit for the Medical Home Model financial risk standard, we are proposing to amend our methodology for identifying which eligible clinicians are to be included under the 50 eligible clinician limit.

Specifically, we propose to amend § 414.1415(c)(7) to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity. We would identify the eligible clinicians in the APM Entity by using the TIN/NPIs on the participation list of the APM Entity on each of the three QP determination dates (March 31, June 30, and August 31). This proposal, if finalized, would become effective beginning in Performance Year 2023. We believe this change will address the challenges we have faced in implementing this policy, as discussed above.

We are also proposing to amend § 414.1420(d)(8) to apply the 50 eligible clinician limit directly to the APM Entity participating in Aligned Other Payer Medical Home Model and Medicaid Medical Home Model, and to no longer look to the parent organization for the APM Entity, consistent with our longstanding practice of aligning Advanced APM policies with Other Payer Advanced APM policies to the extent feasible and appropriate.

In order to continue to achieve our aim of reducing the possibility for an APM Entity to potentially manipulate their numbers of eligible clinicians to inappropriately take advantage of participation in an Advanced APM that is a Medical Home Model, we propose that the Medical Home Model financial risk and nominal amount standards under § 414.1415(c)(2) and (c)(4) would apply only if the APM Entity remains below the 50 eligible clinician limit on all three QP determination dates during the QP Performance Period. If the number of eligible clinicians in the APM Entity is above 50 on any of the three QP determination dates, the Medical Home Model financial risk and nominal amount standards will not apply for that APM Entity for the QP Performance Period. Should an APM Entity exceed the 50 eligible clinician limit on any of the three snapshot dates, no eligible clinicians would achieve or retain QP status through that APM Entity for the QP Performance Period and corresponding payment year, regardless of the outcome of QP determinations made at another QP determination date. We propose to amend the regulation text to says that an APM Entity's Participation List will be used to determine if the 50 eligible clinician limit requirement has been met three times a year, for each of the three QP determination dates (March 31, June 30, and August 31).

In addition, we propose to amend § 414.1440(e)(2) to require APM Entities or eligible clinician requesting a QP determination under the All-Payer Combination Option through participation in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model to supply information and certify that the 50 eligible clinician limit is being met for any Aligned Other Payer Medical Home Model or Medicaid Medical Home Model in which they participate and for the applicable time period in which the APM Entity or eligible clinician QP determination is made under the All-Payer Combination Option, as specified in the proposed revised § 414.1420(d)(8). Note, a practice exceeding the 50 eligible clinician limit under the Medicare Option would not preclude an eligible clinician or APM Entity from seeking a QP determination based on an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model.

We believe this modification to the methodology used to apply the 50 eligible clinician limit would better identify the eligible clinicians and APM Entities that should be included in QP determinations for participation in Advanced APMs under the Medical Home Model financial risk standard, and therefore continue to encourage movement into value based payment arrangements. This methodology would not attempt the complex task of gathering information on parent organizations, and we believe it would treat similarly situated entities similarly.

We seek public comment on these proposals.

(2) Qualifying APM Participant Determination

(a) General Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77448), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible

clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates of that year. An eligible clinician can be determined to be a QP only if they appear on the Participation List on a snapshot date that we use to identify the APM Entity group and to calculate Threshold Scores and make QP determinations at the APM Entity level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List with more than one APM Entity, but do not to achieve QP status based on any APM Entity group-level determinations, we make most QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians who appear on an Affiliated Practitioner list for an Advanced APM we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

(b) Request for Information: Potential Transition to Individual QP Determinations Only

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we discussed our reasons for establishing a policy to calculate Threshold Scores and make most QP determinations at the APM Entity group level, rather than at the individual eligible clinician level. At that time, we believed that this policy promoted administrative simplicity and collaboration among group members instead of imposing barriers or burden. We recognized that while many beneficiaries are attributed to an APM Entity based on the services rendered by one eligible clinician, many of the eligible clinicians participating in the APM Entity play a role in the actual diagnosis, treatment, and management of the many beneficiaries in the APM Entity's patient population. Each of these individual eligible clinicians can potentially be viewed as being instrumental to providing quality care to the beneficiary in alignment with the objectives of the APM, regardless of whether the specific services they furnish are used for purposes of APM-specific attribution methods. We noted that an APM Entity faces the risks and rewards of participation in an Advanced APM as a single unit and generally is responsible for performance metrics that are aggregated to the level of that APM Entity. The policy is based on the premise that entire organizations commit to participating in an Advanced APM and focusing on the attendant cost and quality goals as a whole.

Under the current policy at § 414.1425(b), for most eligible clinicians participating in Advanced APMs, QP determinations are made at the APM Entity level. As described in § 414.1435, the Threshold Score for an APM Entity or eligible clinician is calculated in one of two ways, either the payment amount method or patient count method. The threshold score using the payment count method is calculated by dividing: (1) the aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period; by (2) aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the QP Performance Period. The Threshold Score using the patient count method is calculated by dividing: (1) the number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services; by (2) the number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services. Attributed beneficiaries are generally determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology.

The current policy for QP determinations under the All-Payer Combination Option at § 414.1440(d) establishes a process that is similar to the QP determination participating in Advanced APMs, but accounts for participation in Other Payer Advanced APMs. Under the All-Payer Combination Option, an eligible clinician may request the QP determination be made at the individual or APM Entity level, and an APM Entity may request that the QP determination made at the individual, TIN or APM Entity level. Further, § 414.1440(d) specifies that CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold Score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

We are requesting public comment on the idea of transitioning away from an APM Entity level QP determination and instead calculating Threshold Scores and making QP determinations at the individual eligible clinician level for all eligible clinicians in Advanced APMs and Other Payer Advanced APMs. We believe making QP determinations at the individual eligible clinician level may have several benefits over the current policy. First, as explained later in this section of the proposed rule, we believe that making all QP determinations at the individual eligible clinician level would substantially reduce the practice of APM Entities removing specialists from their participation lists. Second, the change to make all QP determinations at the individual eligible clinician level would increase the number of eligible clinicians who are determined to be QPs for whom their individual participation would qualify them, but whose APM Entities did not qualify because other eligible clinicians in the APM Entity reduced its Threshold Score. Third, if we were to begin making all QP determinations at the individual eligible clinician level, that approach would eliminate the number of eligible clinicians who become QPs for a year, but whose individual participation in their Advanced APM(s) is well below the Threshold Score. Under our current policy to make most QP determinations at the APM Entity level, many eligible clinicians who would not meet the Threshold Score individually but whose APM Entities met the Threshold Score are able to gain QP status. For at least some of those eligible clinicians, a significant portion of the covered professional services they furnish may occur outside of the Advanced APM. When such eligible clinicians receive QP status, they may receive a financial windfall because their APM Incentive Payments are calculated based on all of the covered professional services they furnish during the base year, not just the services they furnish as part of the APM Entity in the Advanced APM.

We note that this potential for receiving a financial windfall is possible through the 2022 QP Performance Period (which correlates to payment year 2024), but this will change beginning in the 2023 QP Performance Period (which correlates to payment year 2025) because the current statute does not provide for any APM Incentive

Payment for that year. As such, there will be no further potential windfall in the form of the APM Incentive Payment.

However, there could be a similar windfall beginning in CY 2026 (which corresponds to the 2024 QP Performance Period) because eligible clinicians who achieve QP status beginning in that year will be paid under the PFS using the differentially higher QP conversion factor for the year, which will apply to all the covered professional services the eligible clinician furnishes in the year. In addition, beginning in payment year 2025 there are competing incentives under the QPP between the MIPS and APM track which are discussed in detail in section IV.(A).(11)(d) of this proposed rule.

Because the APM Entity Threshold Scores (using the payment amount and patient count methods) that are used to make APM Entity-level QP determinations are based on an aggregate calculation across all eligible clinicians participating in the APM Entity group, eligible clinicians in the APM Entity group who furnish proportionally fewer services that lead to attribution of patients or payment amounts to the APM Entity are likely to lower the APM Entity's Threshold Score. For example, primary care physicians may furnish proportionally more evaluation and management (office visit) services which are frequently the basis for attribution of patients and payment amounts to the numerator of the APM Entity's Threshold Score; whereas specialist physicians may furnish proportionally more diagnostic tests and surgical procedures which are not usually part of the attribution basis to the APM Entity.

We have received reports from Advanced APM participants that some APM Entities have taken steps to reduce the number of such eligible clinicians on their Participation Lists. Specifically, to achieve higher QP Threshold Scores, some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating threshold scores for APM Entity-level QP determinations. There are important reasons that it is not beneficial for an APM Entity to exclude specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. In both the Medicare Shared Savings Program and in models tested by the Innovation Center that the meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is essential for achieving this goal. For example, a comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.[531] The methodology used in beneficiary assignment for the Shared Savings Program is deliberately constructed such that assignment is largely based on primary care, rather than specialty care, which results in specialists contributing proportionately less in terms of payment amounts and patient counts to the ACO's QP numerator.

Similarly, it was not our intent to create a policy wherein eligible clinicians who are seeing most or all of their Medicare patients through an Advanced APM may remain unable to achieve QP status because the APM Entity with which they participate in the Advanced APM includes eligible clinicians who furnish very few services through the Advanced APM. It has always been one of the goals of the APM track of the Quality Payment Program for the availability of QP status to incentivize eligible clinicians to join Advanced APMs. But under our current policy to make most QP determinations at the APM Entity level, there is the potential that eligible clinicians who are fully engaged in an Advanced APM may still be unable to earn QP status.

We carefully considered our policy to make most QP determinations at the APM Entity level, and believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and their full participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care.

Finally, we are concerned that, under our current policy to make most QP determinations at the APM Entity level, some eligible clinicians who furnish relatively fewer of their services through an APM Entity may receive a disproportionate financial benefit because they achieve QP status as a result of the care furnished by other eligible clinicians in the APM Entity, while their APM Incentive Payment is calculated based on all of the covered professional services they furnish during the base year—both as part of the APM Entity and elsewhere. Our policy to make most QP determinations at the APM Entity level allows these windfall financial rewards because we calculate the Threshold Scores using the aggregate of payment amounts or patient counts for attributed patients based on Medicare Part B covered professional services furnished by all the eligible clinicians in the APM Entity, whether they furnished a few or many of such services. Once an eligible clinician receives QP status for a year, the APM Incentive Payment is calculated based on paid claims for that individual QP's covered professional services across all their TINs in the base year. This can allow an eligible clinician with minimal Advanced APM participation to receive a large APM Incentive Payment, which we do not believe aligns with the intent of the Quality Payment Program. Though, as we note above, QPs for payment year 2025 (QP Performance Period 2023) will not, by statute, receive a financial incentive for achieving such status, beginning in payment 2026 (QP Performance Period 2024) financial incentives once again will apply in the form of the enhanced QP conversion factor, which in turn compounds each year after that and therefore increases over time.

We are requesting input from interested parties on the possibility of discontinuing our policy to calculate Threshold Scores and make most QP determinations at the APM Entity level, and instead to make all QP determinations at the individual eligible clinician level. We believe this would avoid the potential incentive for APM Entities to limit or exclude specialists and other eligible clinicians who furnish services that are an important part of the health care spectrum, but less likely to be attributed to the APM Entity for purposes of calculating Threshold Scores for QP determinations. While the exclusion from an APM Entity of such specialists and other eligible clinicians can serve to improve the Threshold Scores for an APM Entity, it would not necessarily serve the central goals of many of our Advanced APMs, such as the statutory charge to Medicare Shared Savings Program ACOs to encourage groups of doctors, hospitals, and other health care providers to work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO.

In light of this potential conflict between Advanced APM goals and the existing QP Threshold Score calculation methodology, we are considering

[531] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.*

whether it would be better to make all QP determinations at the individual eligible clinician level using the unique National Provider Identifier (NPI) associated with an eligible clinician participating in an Advanced APM. Under that approach, we would calculate a Threshold Score for each eligible clinician, identified by their NPI, based on all the covered professional services furnished by that individual eligible clinician, including services billed across all of the TINs to which the individual has reassigned their Medicare billing rights. This Threshold Score calculated at the individual eligible clinician level would provide a more specific measurement of each such eligible clinician's level of participation in one or more Advanced APMs. This methodology to calculate Threshold Scores and make QP determinations at the individual eligible clinician level would ensure that only those eligible clinicians (NPIs) who individually meet or exceed the applicable Threshold Score would receive QP status. At the same time, it would allow APM Entities to make decisions about which eligible clinicians to include on their Participation Lists based on the scope of eligible clinicians needed to furnish services to their patient populations under the Advanced APM, and to include those eligible clinicians who furnish proportionally fewer services that lead to patient attribution to the APM Entity under the current QP determination policy, without potentially affecting the QP status of other eligible clinicians in the APM Entity group. Because APM Entities no longer would have a need to consider how each eligible clinician may affect their aggregate Threshold Score for the APM Entity group, they would be able to include any eligible clinician who they believe can help them meet the patient-centered care goals of the Advanced APM(s) they are participating in. Therefore, we are considering whether a change to make QP determinations at the individual eligible clinician level would have a positive health equity impact by ensuring that incentives under the Quality Payment Program would hold ACOs ''accountable for the quality, cost, and experience of care of an assigned Medicare fee-for-service (FFS) beneficiary population.'' [532]

Additionally, an analysis conducted by CMS found that many eligible clinicians do in fact frequently provide covered professional services to beneficiaries attributed to other APM Entities. These types of services and relationships are not necessarily accounted for or rewarded under the current methodology that makes QP determinations predominantly at the APM Entity level because they are outside the APM Entity participating in the Advanced APM, but would be if QP determinations were made at the individual eligible clinician level because all of the relevant covered professional services furnished by that eligible clinician would be counted in the QP determination. While our initial decision to calculate Threshold Scores and make most QP determinations at the APM Entity level was appropriate and, at the time, preferable to achieve the policy goals as stated in the CY 2017 proposed rule and reiterated above, for the reasons we identify here, we also believe that a change to calculate Threshold Scores and make QP determinations at the individual eligible clinician level may be preferable.

In this Request for Information, we are requesting public feedback on whether an individual level QP determination approach is an avenue we should continue exploring in future years to better identify and reward individual eligible clinicians with substantial engagement in Advanced APMs.

(c) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019. The All-Payer Combination Option, which uses the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning in the payment year 2021. In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

In the CY 2022 PFS final rule (86 FR 65557 through 65558), we finalized policies to implement section 114(a) of Subtitle B of Title I of Division CC of the CAA (referred to herein as section 114(a) of Division CC of the CAA), which amended section 1833(z)(2)(B) of the Act with regard to payment years 2023 and 2024 (which correspond respectively to performance years 2021 and 2022), by freezing for such years the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. However, we neglected to fully amend our regulations at § 414.1430(a) and (b) to reflect these changes, and therefore, we are proposing conforming changes to § 414.1430(a) and (b) in this proposed rule.

Specifically, section 114(a) of Division CC of the CAA amended section 1833(z)(2)(B) of the Act to continue the QP payment amount thresholds that apply in payment years 2021 and 2022 for payment years 2023 and 2024. Additionally, section 114(a) of Division CC of the CAA amended section 1833(z)(2)(D) of the Act to require that, for payment years 2023 and 2024, the Secretary must use the same percentage criteria for the QP patient count threshold that are applied in payment year 2022. As such, the Medicare Option QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. Section 114(b) of Division CC of the CAA amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2024 the Partial QP thresholds that are established for payment years 2021 and 2022. Therefore, the Partial QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 40 percent for the payment amount method and 25 percent for the patient count method. For performance years beginning with 2023 (corresponding to payment years beginning with 2025) the statute prescribes the QP thresholds for the payment amount method, and the QP thresholds we established for the patient count method at § 414.1430 will take effect. Specifically, for performance years beginning with 2023, the Medicare Option QP Thresholds will be 75 percent for the payment amount method and 50 percent for the patient count method. The Partial QP Thresholds under the Medicare Option will be 50 percent for the payment amount method and 35 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 40 percent for the payment amount

[532] Ibid.

method and 25 percent for the patient count method. The Partial QP thresholds for performance year 2023 and later (corresponding to payment years 2025 and later) will be 50 percent for the payment amount method and 35 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain threshold percentages under the Medicare Option. For performance years 2021 and later (corresponding to payment year 2023 and later), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent under the patient count method.

TABLE 92: QP Threshold Score Updates

Medicare Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50		50		75	
Partial QP Payment Amount Threshold	40		40		50	
Medicare Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35		35		50	
Partial QP Patient Count Threshold	25		25		35	
All-Payer Combination Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50	25	50	25	75	25
Partial QP Payment Amount Threshold	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 93 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

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TABLE 93: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Administrative Support Worker	43-9000	18.98	18.98	37.96
Anesthesiologists	29-1211	159.22	159.22	318.44
Billing and Posting Clerks	43-3021	20.55	20.55	41.10
Bookkeeping, Accounting, and Auditing Clerks	43-3031	21.70	21.70	43.40
Computer System Analysts	15-1211	49.14	49.14	98.28
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine Physicians	29-1216	116.44	116.44	232.88
Licensed Practical and Licensed Vocational Nurses	29-2061	24.93	24.93	49.86
Medical and Health Services Managers	11-9111	57.61	57.61	115.22
Obstetricians and Gynecologists	29-1218	142.41	142.41	284.82
Office and Administrative Support Workers, All Other	43-9199	20.47	20.47	40.94
Pediatricians, General	29-1221	95.40	95.40	190.80
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1229	111.30	111.30	222.60
Psychiatrists	29-1223	120.08	120.08	240.16
Secretaries and Administrative Assistants	43-6014	19.75	19.75	39.50
Surgeons, Except Ophthalmologists	29-1249	143.17	143.17	286.34

TABLE 94: Physician Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	159.22	159.22	318.44
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine Physicians	29-1216	116.44	116.44	232.88
Obstetricians and Gynecologists	29-1218	142.41	142.41	284.82
Pediatricians, General	29-1221	95.40	95.40	190.80
Physicians, All Other	29-1229	111.30	111.30	222.60
Psychiatrists	29-1223	120.08	120.08	240.16
Orthopedic Surgeons, Except Pediatric	29-1242	147.22	147.22	294.44
Pediatric Surgeons	29-1243	139.57	139.57	279.14
Surgeons, All Other	29-1249	143.17	143.17	286.34
Surgeons	29-1240	141.60	141.60	283.20
Total	2,859.69			
Average Wage (2,859.68/11)	259.98			

As indicated, we adjusted BLS' hourly wage estimates by a factor of 100 percent to obtain the adjusted hourly wage estimate. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§ 414.940)

As discussed in section III.A.7. of this proposed rule, as a part of implementing section 1847A(h) of the Act, as added by section 90004 of the Infrastructure Act, we recognize the need for establishing a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. We are proposing that each manufacturer have an opportunity to dispute the report, described in section III.A.4. of this proposed rule, by submitting an error report.

We are proposing that to assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error. The dispute must include the following information: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why the Secretary should use the proposed corrected data instead.

As discussed in section VII.E.1. of this proposed rule, our estimates show a projected 26 billing and payment codes meeting the proposed definition of refundable single-dose container or single-use package drug would have 10 percent or more discarded units, which is the applicable percentage specified in section 1847A(h)(3) of the Act. Therefore, we anticipate a similar number of drugs would owe a refund pursuant section 90004 of the Infrastructure Act. Since each of these billing and payment codes is a single source drug code, each would represent 1 manufacturer and we would expect disputes from fewer than 10 manufacturers per year.

Consistent with the estimated annual burden per respondent/recordkeeper for similar error reports utilized to implement the Branded Prescription Drug Fee (76 FR 51310), we estimate the annual burden per respondent/recordkeeper to be 40 hours. If we anticipate no more than 10 disputes per year, the total annual reporting and/or recordkeeping burden would be 400 hours (10 error reports per year × 40 hours per respondent). Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2021) for Category 43–6014 (Secretaries and Administrative Assistants), the mean hourly wage for an administrative assistant is $19.75.[533] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $39.50 ($19.75 + $19.75). Therefore, we estimate an annual cost of this burden to be $15,800 ($39.50/hour × 400 hours). These information collection requirements discussed in this section will be submitted to OMB for approval as part of a new information collection request.

2. ICRs Regarding the Clinical Laboratory Fee Schedule: Data Reporting by Laboratories

As described in section III.B of this proposed rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' As stated in section 1834A(h)(2) of the Act, Chapter 35 of title 44, United States Code, shall not apply to information collected under section 1834A of the Act. Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to section VII.F.8. of this proposed rule for a discussion of the impacts associated with the proposed changes to the Shared Savings Program as described in section III.G. of this proposed rule.

4. ICRs for Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

In section III.I. of this proposed rule, we propose to clarify § 410.40(e)(2)(ii) by reorganizing existing language and stating that the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is required. We are also clarifying that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance. Finally, we are clarifying that coverage includes observation or other services rendered by qualified ambulance personnel. We do not expect that our proposal will yield a change in the information collection burdens currently approved under OMB control number 0938–1380 and 0938–0969 as this policy does not require providers and suppliers to submit additional information. We are simply clarifying existing policy requirements.

5. ICRs for Medicare Provider and Supplier Enrollment Changes

We propose the following three revisions to § 424.518:

- Add changes of ownership and the reporting of a new owner as provider enrollment transactions falling within the scope of § 424.518. (As explained in section III.J. of this proposed rule, these parties would have to submit fingerprints and be subject to a fingerprint-based criminal background check (FBCBC) if the provider or supplier is in the ''high'' level of categorical screening.)
- State that any screening level adjustment to ''high'' also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier that originally triggered the screening level increase.
- Moving SNFs from the ''limited'' level of categorical screening to the ''high'' screening level.

[533] *https://www.bls.gov/oes/current/oes436014.htm.*

These proposed changes would result in an increase in the annual number of providers and suppliers that must submit the fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) of all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. The burden is currently approved by OMB under control number 1110–0046. An analysis of the impact of this requirement can be found in the RIA section of this rule.

None of our other proposed Medicare provider enrollment provisions implicate information collection requirements.

6. ICRs for State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

We do not anticipate any information collection burden associated with our proposed revision to § 455.107(b), for the latter merely involves giving the states somewhat greater flexibility in executing the provisions of § 455.107.

7. ICRs Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.M. of this proposed rule, we are proposing to extend the existing compliance action of sending letters to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024 through December 31, 2024). Additionally, effective January 1, 2023, we are proposing to change the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions (§ 423.160(a)(5)(ii)). We are also proposing to determine whether a prescriber qualifies for the emergency or disaster exception (§ 423.160(a)(5)(iii)) based on the prescriber's valid address in PECOS (Medicare Provider Enrollment, Chain, and Ownership System), instead of the NCPDP Pharmacy Database address, and for prescribers who are not enrolled or do not have a valid PECOS address, we are proposing to use the address in the National Plan and Provider Enumeration System (NPPES) data. We do not expect that our proposal will yield a change in the information collection burdens currently being submitted for review under OMB control number 0938–1396 (CMS–10755) as these proposals do not require providers and suppliers to submit additional information. We refer readers to the 2022 PFS final rule (86 FR 65562 through 65564) for a detailed discussion of the EPCS collection of information burden that is being submitted under OMB control number 0938–1396.

8. ICRs Regarding the Medicare Ground Ambulance Data Collection System (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, this collection of information section does not set out any burden for the proposed provisions. Please see section VII. of this preamble for a discussion of the estimated impacts.

9. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Proposed Rule)

The following QPP-specific ICRs reflect this proposed rule's policy changes as well as adjustments to the policies that have been finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 59452, 84 FR 62568,85 FR 84472, and 86 FR 64996 respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

There is a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the proposed changes in the estimated burden for the information collections relevant to the revisions in the policies associated with the CY 2023 PFS proposed rule and the proposed revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The proposed estimated burden will be submitted to OMB under control number OMB 0938–1314 (CMS–10621). The collection of information associated with the CAHPS for MIPS survey under OMB control number 0938–1222 (CMS–10450) is currently pending OMB review and approval. We note that CMS has already received approval for collection of information associated with the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(2) Summary of Quality Payment Program Changes: MIPS

We have included the change in estimated burden for the CY 2023 performance period/2025 MIPS payment year due to the proposed policies and information collections in this proposed rule. The proposed policies in this rule impact the burden estimates for the CY 2023 MIPS performance period/2025 MIPS payment year.

The following six MIPS ICRs show changes in burden due to the proposed policies in this rule: (1) Quality performance category data submission by Medicare Part B claims collection type; (2) Quality performance category data submission by QCDR and MIPS CQM collection type; (3) Quality performance category data submission by eCQM collection type; (4) MVP quality performance category submission; (5) MVP registration, and (6) Promoting Interoperability performance category data submission. In aggregate, we estimate the proposed policies would result in a net decrease in burden of 11,039 hours and $1,213,933 for the CY 2023 performance period/2025 MIPS payment year. The remaining changes to our currently approved burden estimates are adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this proposed rule.

We have added one new ICR for third party intermediaries to distinctly capture the burden for collection of information related to: (1) QCDR and qualified registry targeted audits as established under the conditions for approval at § 414.1400(b)(3)(vi) through (viii); and (2) all the requirements for remedial action and termination at § 414.1400(e). For simplicity, we capture the estimated burden for third party intermediaries to submit additional requirements for compliance with both the conditions of approval and remedial action and termination criteria under one ICR. We note that the proposed addition of this ICR is not due to proposed policy changes in this rule, but rather it is a change in our approach to representing the estimated burden for third party intermediaries in the CY 2022 PFS final rule. (86 FR 65569 through 65576)].

We are not making any changes or adjustments to the following ICRs:

Registration for virtual groups; CAHPS survey vendor applications; group registration for CAHPS for MIPS survey; CAHPS for MIPS survey beneficiary participation; subgroups registration; call for quality measures; call for Promoting Interoperability measures; call for quality measures; nomination of improvement activities and opt-out of performance data display on Compare Tools for voluntary participants. See section V.B.9. of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted by two primary factors. First, we are unable to predict with absolute certainty who will be a QP for the CY 2023 performance period/2025 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the CY 2023 performance period/2025 MIPS payment year compared to the CY 2019 performance period/2021 MIPS payment year, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data. Additionally, we will continue to update our estimates annually as data becomes available.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the CY 2023 performance period/2025 MIPS payment year. We did not implement any changes to the Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of Data for QP determinations under the All-Payer Combination Option.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 95 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 95, MIPS eligible clinicians and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in a MIPS Value Pathway (MVP). We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS.

Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 95.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule that the APP is available for both ACO participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2023 performance period/2025 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in the CY 2022 PFS final rule (86 FR 65259 through 65263), the CMS Web Interface collection type is available through the CY 2024 performance period/2026 MIPS payment year only for clinicians participating in the Shared Savings Program. Per section 1899 of the Act (42 U.S.C. 1395jjj), submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. As described in section IV.A.10.c.(5)(b) of this proposed rule, we are proposing to introduce a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 QPP final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 PFS final rule (82 FR 53841 through 53844).

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TABLE 95: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures (CMS Web Interface will be available to only clinicians in ACOs **through** the CY **2024** performance period/**2026** MIPS payment year)	As a virtual group, group, subgroup, individual clinician, or APM Entity.[a]	As a virtual group, group, subgroup, individual clinician, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or APM Entity TIN or individual reporting. [The burden estimates for this proposed rule assume group TIN-level reporting]. [b]	As a virtual group, group, subgroup, or individual clinician. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. MVP participants electing to submit data for the measures and activities in an MVP must register. Clinicians in MIPS APMs electing the APM Performance Pathway. (CMS Web Interface will be available to only clinicians in ACOs **through** the CY **2024** performance period/**2026** MIPS payment year.) APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email. [d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by the ACO are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Section 1899 of the Act (42 U.S.C. 1395jjj) states that the Shared Savings Program is not subject to the PRA.

[b] Promoting Interoperability performance category data may be submitted at the group TIN, APM Entity TIN and individual clinician level. If group TIN, APM Entity TIN, and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. For multi-TIN APM Entities that do not submit at the APM Entity level, the TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472 and 86 FR 64996), and continued in this proposed rule create some additional data collection requirements not listed in Table 95. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs related to MIPS third-party intermediaries (see section V.B.9.c. of this proposed rule):

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314)
- Third party intermediary plan audits (New)
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 through 84970).

Additional ICRs related to the data submission and the quality performance category (see section V.B.9.e. of this proposed rule):

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs related to the Promoting Interoperability performance category (see section V.B.9.g. of this proposed rule):

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities (see sections V.B.9.f., V.B.9.h., and V.B.9.j. of this proposed rule):

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314).

Additional ICRs related to MIPS (see section V.B.9.o. of this proposed rule):

- Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections V.B.9.m. and V.B.9.n. of this proposed rule):

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not proposing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not proposing any changes to the virtual group election process under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

In this rule, we propose changes in our existing approach to capture the estimated burden for third party intermediaries. In the CY 2022 PFS final rule, for the burden related to the third party intermediaries, we combined the burden associated with the submission of targeted audits, corrective action plans, participation plans and transition plans under the ICRs for QCDR and qualified registry self-nomination process (86 FR 65569 through 65573 and 86 FR 65573 through 65576). We propose to separate the burden for submission of the targeted audits and other plans listed above under the ICR for third party intermediary plan audits (see section V.B.9.c.(4) of this proposed rule). We believe that the proposed change would more accurately capture the associated burden for the QCDR and qualified registry self-nomination process because not every QCDR or qualified registry that submits a self-nomination application would also submit a targeted audit, corrective action plan (CAP), participation plan, or a transition plan. This change is not due to any proposed policies related to third party intermediaries in this rule, rather it is a change in representing the estimated burden from adopted policies. The proposed requirements and burden associated with this rule's self-nomination process related to qualified registries and QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.10.g.(1)(b) of this rule, we propose updates to the definition of a third party intermediary at § 414.1305, and to make other minor conforming technical edits to the regulation text governing third party intermediaries set forth in § 414.1400. We also propose to revise QCDR measure self-nomination and measure approval requirements to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[534] The processes for self-nomination of entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

As described below, in this rule we propose to adjust the number of self-nomination applications used to

[534] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

calculate our burden estimates based on current data (from 84 to 90). We are not proposing adjustments to the number of QCDR measures submitted for consideration by each QCDR at the time of self-nomination and the average time required to submit information for each QCDR measure. We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 through 77508, 82 FR 53906 through 53908), the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969 and 86 FR 65569 through 65573) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

(a) Self-Nomination Process and Other Requirements

In section IV.A.10.g.(1)(b) of this rule, we propose to update the definition of a third party intermediary at § 414.1305 to include subgroups and APM Entities and to make minor edits for technical clarity. We propose the revised definition would provide that a third party intermediary means an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities and Promoting Interoperability performance categories. This proposal is intended to update the regulation text to align with the existing policy and does not require additional information from QCDRs during the self-nomination process. Therefore, we are not proposing to revise our burden estimates related to this proposal.

(b) QCDR Measure Requirements

We previously finalized QCDR measure self-nomination requirements at § 414.1400(b)(4)(i), including the requirement at § 414.1400(b)(4)(i)(B) that entities must publicly post the measure specifications for QCDR measures no later than 15 calendar days following CMS approval of any QCDR measure specifications.

In section IV.A.10.g.(2)(b) of this rule, we propose to revise § 414.1400(b)(4)(i)(B) to clarify requirements for publicly posting the QCDR measure specifications. We are not adjusting our burden estimates as a result of this proposal because this would not substantively change the estimated time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

Additionally, in section IV.A.10.g.(2)(c) of this rule, we propose to amend § 414.1400(b)(4)(iii)(A)(*3*) to delay the requirement for QCDR measure full testing until the CY 2024 performance period/2026 MIPS payment year. We are not adjusting our burden estimates as result of this proposal because we assume that this does not meaningfully change the existing requirements, or the time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

For this rule, we propose to adjust the number of estimated QCDRs that would submit applications for self-nomination from 84 to 90 based on the number of applications that we expect to receive during the CY 2022 self-nomination period for the CY 2023 performance period/2025 MIPS payment year. This is an increase of 6 from the currently approved number of 84 respondents in the CY 2022 PFS final rule (86 FR 65571). We are not proposing any changes to the currently approved time of 0.5 hours required for the QCDR simplified self-nomination process and 2.5 hours for the full self-nomination process in the CY 2022 PFS final rule (86 FR 65571). Additionally, this rule is not proposing any new requirements for QCDRs that nominate QCDR measures as part of the self-nomination process. Therefore, we are not proposing changes to revise our currently approved estimated time for the QCDRs that submit measures as part of their self-nomination process (9.5 hours for the simplified self-nomination process and 11.5 hours for the full self-nomination process respectively) (86 FR 65571).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on behalf of MIPS eligible clinicians.

As shown in Table 96, we assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. Using the change in the number of respondents, in aggregate, the proposed estimated annual burden for the simplified and full-self nomination process will range from 855 hours (90 QCDRs × 9.5 hr) to 1,035 hours (90 QCDRs × 11.5 hr) at a cost ranging from $84,029 (855 hr × $98.28/hr) and $101,720 (1,035 hr × $98.28/hr), respectively.

TABLE 96: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	90	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	90
Total Applications (c)	**90**	**90**
Annual Hours Per QCDR for Simplified Process (d)	9.5	0
Annual Hours Per QCDR for Full Process (e)	0	11.5
Total Annual Hours for Self-nomination (f) = (a) * (d) and (b) * (e)	**855**	**1,035**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $98.28/hr) (g) = (d) * $98.28/hr	$933.66	0
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $98.28/hr) (h) = (e) * $98.28/hr	0	$1,130.22
Total Annual Cost (**i**) = (a) * (**g**) (min) and (b) * (**e**) (max)	**$84,029**	**$101,720**

As shown in Table 97, for the CY 2023 performance period/2025 MIPS payment year, the proposed change in the representation of burden for this ICR described above in this section and the estimated increase in 6 respondents

from the currently approved 84 respondents to 90 results in a change of −63 hours at a cost of −$6,192 for the simplified self-nomination process (or minimum burden) and −141 hours at a cost of −$13,857 for the full self-nomination process (or maximum burden). We note that the decrease in burden is due to separating the estimated burden for targeted audits, CAPs, and participation plans and including that burden under a new ICR for third party intermediary plan audits (see Table 101).

We note that for the purposes of calculating proposed estimated change in burden in Tables 132, 133, and 135 of this rule, we use only the maximum burden estimate.

TABLE 97: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Hours (a)	918	1,176
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 96, row (f))	855	1,035
Difference (c) = (b) - (a)	**-63**	**-141**
Total Currently Approved Annual Cost (d)	$90,221	$115,577
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 96, row (i))	$84,029	$101,720
Difference (f) = (e) - (d)	**-$6,192**	**-$13,857**

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to § 414.1400 which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

In section IV.A.10.g.(1)(b) of this rule, we propose to update the definition of a third party intermediary at § 414.1305 to include subgroups and APM Entities and to make minor edits for technical clarity. This proposal would update the regulation text to align with existing policy and does not require additional information from qualified registries during the self-nomination process. Therefore, we are not proposing to revise our burden estimates related to this proposal.

For this rule, we propose to adjust the number of estimated qualified registries that would submit applications for self-nomination from 147 to 160 based on the number of applications that we expect to receive during the CY 2022 self-nomination period for the CY 2023 performance period/2025 MIPS payment year. This is an increase of 13 applications from the currently approved estimate of 147 in the CY 2022 PFS final rule (86 FR 65574). Therefore, we are proposing to revise our estimates for this information collection related to the qualified registry self-nomination process. We are not proposing changes to revise our currently approved estimated time of 0.5 hours for the simplified qualified registry self-nomination process and 2 hours for the full qualified registry self-nomination process (86 FR 65574 through 65575).

As shown in Table 98, we assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. Using the proposed change in estimated number of respondents, combined with the estimated time required for a self-nomination process ranging from a minimum of 0.5 hours to a maximum of 2 hours, we estimate that the annual burden would range from 80 hours (160 qualified registries × 0.5 hr) to 320 hours (160 qualified registries × 2 hr) at a cost ranging from $7,862 (80 hr × $98.28/hr) and $31,450 (320 hr × $98.28/hr), respectively.

Both the proposed minimum and maximum burden shown in 99 reflect the adjustments to the number of respondents due to availability of more recent data. Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 98: Estimated Burden for Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	160	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	160
Total Applications (c)	**160**	**160**
Annual Hours Per Qualified Registry for Simplified Process (d)	0.5	0
Annual Hours Per Qualified Registry for Full Process (e)	0	2
Total Annual Hours for Self-Nomination for min. (f) = (a) * (d) and max. (b) * (e)	**80**	**320**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $98.28/hr) (g)	$49.14	0
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $98.28/hr) (h)	0	$196.56
Total Annual Cost **(i)** = (a) * **(g) (min.)** and (b) * **(h) (max.)**	**$7,862**	**$31,450**

As shown in Table 99, for the CY 2023 performance period/2025 MIPS payment year, the proposed change in the representation of burden for this ICR described above in this section and the estimated increase in 13 respondents from the currently approved 147 respondents to 160 results in a change of −311 hours at a cost of −$30,565 for the simplified self-nomination process (or minimum burden) and −521 hours at a cost of −$51,203 for the full self-nomination process (or maximum burden). We note that the decrease in burden is due to separating the estimated burden for targeted audits and participation plans and including that burden under a new ICR for third party intermediary plan audits (see Table 101).

We note that for the purposes of calculating proposed estimated change in burden in Tables 132, 133, and 135 of this rule, we use only the maximum burden estimate.

TABLE 99: Change in Estimated Burden for Qualified Registry Self -Nomination

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Hours (a)	391	841
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 100, row (f))	80	320
Difference (c) = (b) - (a)	**-311**	**-521**
Total Currently Approved Annual Cost (d)	$38,427	$82,653
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 98, row (i))	$7,862	$31,450
Difference (f) = (e) - (d)	**-$30,565**	**-$51,203**

(4) ICR for Third Party Intermediary Plan Audits

As discussed above in this section, we are proposing to add a new ICR to distinctly capture the burden for collection of information related to QCDR and qualified registry targeted audits at § 414.1400(b)(3)(vi) through (viii) and the requirements for remedial action and termination of third party intermediaries at § 414.1400(e) during the third party intermediary self-nomination process. We note that we capture the estimated burden for third party intermediaries to submit additional requirements for compliance with both the conditions of approval and remedial action and termination criteria under one ICR. The proposed requirements and burden associated with developing the plans and audits by QCDRs and qualified registries will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2022 PFS final rule, we combined the burden associated with the submission of the targeted audits, corrective action plans, participation plans and transition plans with the ICR for QCDR self-nomination process and other requirements (86 FR 65569 through 65573) and the ICR for qualified registry self-nomination process and other requirements (86 FR 65573 through 65576). For the purposes of this ICR, we refer to these audits and plans collectively as ''plan audits.'' For this proposed rule, we determined that it is necessary to separately estimate the burden for QCDR and qualified registry targetedaudits from self-nomination application burden because it would more accurately represent the burden.

In section IV.A.10.g.(3) of this rule, we propose a few changes to the regulations remedial actions and terminations set forth in § 414.1400(e). These include one revised and one new requirement for Corrective Action Plans (CAPs), and proposed termination of certain approved QCDRs and qualified registries that continue to fail to submit performance data. The burden associated with these proposals is discussed below.

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 through 65548), we finalized that beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified

registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS final rule for the QCDRs (86 FR 65574) and qualified registries (86 FR 65571) that would submit targeted audits, we estimate that the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume that the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr.

Using the proposed adjustments to the number of QCDRs and qualified registries expected to submit self-nomination applications in sections V.B.9.c.(2) and V.B.9.c.(3) of this rule, we estimate that 70 third party intermediaries (20 QCDRs and 50 qualified registries) would submit targeted audits for the CY 2023 performance period/2025 MIPS payment year (See Table 100). Using the unchanged currently approved time per respondent (86 FR 65572), we estimate the total impact associated with QCDRs and qualified registries completing targeted audits will range from 350 hours (70 respondents × 5 hours/audit) at a cost of $34,398 (70 respondents × $491.40/audit) to 700 hours (70 respondents × 10 hours/audit) at a cost of $68,796 (70 respondents × $982.80/audit) for the simplified and full self-nomination process, respectively (see Table 101 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that have not submitted performance data to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for previously finalized policies for remedial action and termination of third-party intermediaries.

In section IV.A.10.g.(3)(b) of this proposed rule, we propose a new termination policy for approved QCDRs and qualified registries which are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii). We propose to terminate those QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period. Specifically, we propose to add a new ground for termination at § 414.1400(e)(5) stating that, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated. If this policy is finalized, CMS would terminate the qualified registry or QCDR as applicable under § 414.1400(e)(5) and we assume that it would not require additional requirements for interested parties to submit their information during the qualified registry and QCDR self-nomination process. (86 FR 65574). We refer readers to section IV.A.10.g.(3)(b) of this rule for additional details related to these proposals.

Consistent with our assumptions in the CY 2022 PFS final rule for the QCDRs (86 FR 65574) and qualified registries (86 FR 65571) that would submit participation plans, we estimate that it would take 3 hours for a QCDR or qualified registry to submit a participation plan during the self-nomination process. We assume that the staff involved in submitting a participation plan will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr.

As shown in Table 100, we estimate that 29 third party intermediaries (10 QCDRs and 19 qualified registries) would submit participation plans for the CY 2023 performance period/2025 MIPS payment year. Therefore, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans would be 87 hours (29 respondents × 3 hours/plan) at a cost of $8,550 (29 respondents × $294.84/plan). (See Table 101 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In section IV.A.10.g.(3)(a) of this rule, we propose to revise the CAP requirement at § 414.1400(e)(1)(i)(B) to require the third party intermediary to address in its CAP the impact to individual clinicians, groups, or virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed. We also propose to add a new CAP requirement to require the third-party intermediary to notify the parties identified in proposed § 414.1400(e)(1)(i)(B) of the impact to these parties by submitting a communication plan. Additionally, we propose to add § 414.1400(e)(1)(i)(E) to require the third party intermediary to develop a communication plan for communicating the impact to the parties identified in proposed § 414.1400(e)(1)(i)(B). We assume that the intent of this proposal is to enable affected parties to better understand and prepare for any operational and other challenges as needed. We believe having third party intermediaries submit a communication plan as part of their CAP would ensure third party intermediaries directly communicate the situation and its impact to these parties in a timely and consistent manner. However, due to the relatively low number of CAPs (an average of 10 responses) that we expect to receive from QCDRs and qualified registries for the CY 2023 performance period/2025 MIPS payment year, we are unable to estimate the burden associated with the development of a communication plan.

Consistent with our assumptions in the CY 2022 PFS final rule for the QCDRs and qualified registries (86 FR 65575) that would submit CAPs, we estimate that 10 third party intermediaries would submit CAPs for the CY 2023 performance period/2025 MIPS payment year. Additionally, we estimate that it would take 3 hours for a QCDR or qualified registry to submit a participation plan. We assume that the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr.

Therefore, we estimate the total impact associated with QCDRs and qualified registries to CAPs would be 30 hours (10 respondents × 3 hours/plan) at a cost of $2,948 (10 respondents × $294.84/plan). (See Table 101 for the cost per audit).

(d) Transition Plans

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we established a policy at § 414.1400(a)(4)(vi) that a condition of approval for the third party intermediary is to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on

which data has been collected, collection type according to a CMS approved transition plan. In the CY 2020 PFS final rule (84 FR 63115), we did not estimate the total burden associated with the development of CMS approved transition plans because of the uncertain, but low frequency (less than 10 per year historically) with which third party intermediaries have elected to discontinue services during a performance period. Based on updated data received for the transition plans submitted by the registries and QCDRs beginning with the CY 2020 performance period/2022 MIPS payment year, we estimate to receive 15 transition plans from QCDRs and qualified registries for the CY 2023 performance period/2025 MIPS payment year. We estimate that it would take 1 hour for a computer system analyst or their equivalent at a labor rate of $98.28/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. Therefore, we estimate the total impact associated with qualified registries completing transition plans is 15 hours (15 transition plans × 1 hour/plan) at a cost of $1,474 (15 hr × $98.28/hr). We refer readers to section VI.E.16.e.(2)(c) of this proposed rule where we discuss our impact analysis for the transition plans submitted by QCDRs and qualified registries.

In section IV.A.10.g.(3) of this rule, we propose to revise conforming changes to § 414.1400(e)(2), which currently states that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group under certain circumstances. Rather than amend this provision to add references to subgroups and APM Entities, we propose to revise § 414.1400(e)(2) by removing the previously quoted phrase. If this proposal is finalized, the revised regulation would simply provide that CMS may immediately or with advance notice ''terminate a third party intermediary' under the specified circumstances. We assume that these proposals are intended to revise the regulation text in conjunction with the proposal in section IV.A.10.g.(1)(b) of this rule to amend the definition of a ''third party intermediary'' to refer to subgroups and APM Entities, and do not require additional information from qualified registries during the self-nomination process.

In section IV.A.10.g.(4)(b) of this rule, we propose to update § 414.1400(f)(1) to require that the entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email. We assume that the intent of this proposal is to update the regulation text to align with the proposed updates to the definition of a ''third party intermediary'' at § 414.1305. We do not expect to receive additional information from qualified registries during the self-nomination process due to this proposal. Additionally, we refer readers to section VI.E.16.e.(2)(c) of this proposed rule where we discuss our impact analysis for these proposals.

As shown in Table 100, we assume that 124 third party intermediaries would submit plan audits (targeted audits, participation plans, CAPs, and transition plans).

TABLE 100: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	70
# of Participation Plans (b)	29
# of Corrective Action Plans (CAPs) (c)	10
# of Transition Plans (d)	15
Total Respondents (e) = (a) + (b) + (c) + (d)	**124**

As shown in Table 101, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $98.28/hr. For the CY 2023 performance period/2025 MIPS payment year, in aggregate, the proposed estimated annual burden for the simplified (or minimum) and full (or maximum) self-nomination process will range from 482 hours to 832 hours at a cost ranging from $50,370 (482 hr × $98.28/hr) and $81,769 (832 hr × $98.28/hr), respectively.

TABLE 101: Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Minimum	Maximum
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 70 Targeted Audits (b)	**350**	**700**
# of Hours per Submission of Participation Plan (c)	3	3
Total Annual Hours for Submission of 29 Participation Plans (d)	**87**	**87**
# of Hours per Submission of CAP (e)	3	3
Total Annual Hours for Submission of 10 CAPs (f)	**30**	**30**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 15 Transition Plans (h)	**15**	**15**
Total Annual Hours for Submission of Plan Audits (i) = (b) + (d) + (f) + (h)	**482**	**832**
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $98.28/hr) (j) = (a) * $98.28/hr	$491.40	$982.80
Cost Per Participation Plan (@ computer systems analyst's labor rate of $98.28/hr) (k) = (c) * $98.28/hr	$294.84	$294.84
Cost per CAP (@ computer systems analyst's labor rate of $98.28/hr) (l) = (e) * $98.28/hr	$294.84	$294.84
Cost per Transition Plan @computer systems analyst's labor rate of $98.28/hr (m) = (g) * $98.28/hr	$98.28	$98.28
Total Annual Cost (n) = 70 * (j) + 29 * (k) + 10 * (l) + 15 * (m) (min) and 70 * (j) + 29 * (k) + 10 * (l) + 15 * (m) (max)	**$50,370**	**$81,769**

As shown in Table 102, for the CY 2023 performance period/2025 MIPS payment year, the addition of this ICR for third party intermediary plan audits results in a change of +482 hours at a cost of +$50,370 for the simplified self-nomination process (or minimum burden) and +832 hours at a cost of +$81,768 for the full self-nomination process (or maximum burden).

We note that for the purposes of calculating proposed estimated change in burden in Tables 132, 133, and 135 of this rule, we use only the maximum burden estimate.

TABLE 102: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Total Currently Approved Annual Hours (a)	0	0
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 101, row (i))	482	832
Difference (c) = (b) - (a)	**+482**	**+832**
Total Currently Approved Annual Cost (d)	$0	$0
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 101, row (n))	$50,370	$81,769
Difference (f) = (e) - (d)	**+$50,370**	**+$81,769**

(5) Survey Vendor Requirements

This rule is not proposing new or revised collection of information requirements related to the requirements for CAHPS Survey vendors. The requirements and burden for CAHPS survey vendors to submit data for eligible clinicians are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes to the CAHPS for MIPS Survey vendor information collection request under that control number.

d. ICR Regarding Open Authorization (OAuth) Credentialing and Token Request Process

The proposed requirements and burden associated with the OAuth Credentialing and token request process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2021 and the CY 2022 PFS final rules (85 FR 84969 through 85 FR 84970 and 86 FR 65576) for our previously finalized requirements and burden estimates for the information collection related to the OAuth credentialing and token request process.

This rule is not proposing new or revised collection of information requirements related to the OAuth credentialing and token request process. Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, we made administrative

changes in the process for interested parties to submit their application for OAuth credentialing and token process. Based on the changes to the workflows, the CMS Office of Information Technology (OIT) has centralized Okta Administrator privileges. In previous years, the Quality Payment Program maintained the privileges for Administrator roles. As a result of this change, interested parties that would submit their information for OAuth Credentialing and Token request process are now required to meet with both Quality Payment Program and OIT for final approvals to have their applications integrated with the CMS Okta production environment. Therefore, we propose to revise our estimates that it would take 2 hours for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email. This is an increase of 1 hour from the currently approved estimated time of 1 hour for interested parties to provide their documentation and any follow-up communication via email.

As shown in Table 103, we are not proposing any changes to our currently approved estimate of 15 respondents that would complete this process for the CY 2023 performance period/2025 MIPS payment year. In aggregate, accounting for the increase in time required for a computer systems analyst (or their equivalent) to complete the token request process, we estimate an annual burden of 30 hours (15 vendors × 2 hrs) at a cost of $2,948 (30 hrs × $98.28/hr).

TABLE 103: Estimated Burden for the OAuth Credentialing and Token Request Process

Burden and Respondent Descriptions	Burden Estimate
# of Respondents (a)	15
Total Hours per Respondent	2
Total Annual Hours (c) = (a) * (b)	**30**
Labor Rate for Computer System Analyst (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$2,948**

As shown in Table 104, using our unchanged currently approved number of respondents (86 FR 65576), the proposed increase in the amount of time required for the OAuth credentialing and token request process results in an adjustment of +15 hours (+15 respondents × 1 hr/respondent) at a cost of +$1,474 (+15 hr × $98.28/hr) from our currently approved burden of 15 hours (15 respondents x 1 hr/respondent) at a cost of $1,474 (15 hrs × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 104: Change in Estimated Burden for OAuth Credentialing and Token Request Process

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	15
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 103, row (c))	30
Difference (c) = (b) - (a)	**+15**
Total Currently Approved Annual Cost (d)	$1,474
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 103, row (e))	$2,948
Difference (f) = (e) - (d)	**+$1,474**

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 through 77503 and 82 FR 53908 through 53912), the CY 2019, CY 2020, CY 2021, and CY 2022 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, 86 FR 65576 through 65588) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: those who submit data as MIPS eligible clinicians, and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the third snapshot date for the

2021 QP Performance period. From this data, we calculated the QP determinations as Pdescribed in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2023 performance period/2025 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future for the CY 2023 performance period/2025 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). We note that we continue to use CY 2019 performance period/2021 MIPS payment year data to estimate the number of respondents in the CY 2023 PFS proposed rule.

There may be an undercount in submissions due to the PHE for COVID–19, because of the automatic extreme and uncontrollable circumstances policy, and application-based policy that allowed clinicians to elect not to submit during the submission period for the CY 2019 performance period/2021 MIPS payment year that we are using to inform our burden estimates. Despite this limitation, we believe the data from the CY 2019 performance period/2021 MIPS payment year is still the best data source available as it most accurately reflects the impacts of policies finalized in previous rules and trends toward increased group reporting.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2021 and CY 2022 PFS final rules (85 FR 84972 and 86 FR 65567), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.9.a.(4) of this proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2023 performance period/2025 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 performance period/2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2019 performance period/2021 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this proposed rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[535]

For the CY 2023 performance period/2025 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. Additionally, we capture the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2019 performance period/2021 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 105 uses methods similar to those described above to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the CY 2023 performance period/2025 MIPS payment year. For the CY 2023 performance period/2025 MIPS payment year, we estimate that approximately 27,006 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 37,306 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 38,464 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2019 performance period/2021 MIPS payment year, these are increases of 1,579, 850, and 2,063 respondents from the currently approved estimates of 25,427, 36,456, and 36,401 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

[535] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

TABLE 105: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM		Total
2023 MIPS performance period (excludes QPs) (a)	30,689		42,393	43,709	116,791
MVP Adjustment (b) = (a)* 0.12	3,683	5,087	5,245	14,015	
2023 MIPS Performance Period (excludes QPs) (**Adjusted for** MVP) (**c**)	**27,006**	**37,306**	**38,464**	**102,776**	
*Currently approved 2023 MIPS Performance Period (excludes QPs) (d)	25,427	36,456	36,401		98,284
Difference (**e**) = (**c**) – (**d**)	**+1,579**	**+850**	**+2,063**	**+4,492**	

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 105 are not mutually exclusive.

Table 106 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2023 performance periods/2025 MIPS payment year. We assume that clinicians who submitted quality data as groups in the CY 2019 performance period/2021 MIPS payment year will continue to submit quality data either as groups, or virtual groups for the same collection types for the 2023 performance period/2025 MIPS payment years. We refer readers to the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2019 performance period/2021 MIPS payment year.

As shown in Table 106, for the CY 2023 performance period/2025 MIPS payment year we estimate that 10,278 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 7,296 groups and virtual groups will submit for eCQM collection types. These are decreases of 156 and 76 respondents from the currently approved estimates of 10,434, and 7,372 for the groups that would submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

As the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities will participate through traditional MIPS and base our estimates on submissions received in the CY 2019 performance period/2021 MIPS payment year.

TABLE 106: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2023 MIPS performance period (excludes QPs) (a) prior to adjustments	0	11,680	8,291	19,971
Adjustment for MVPs (12%) (b) = (a) * 0.12	0	1,402	995	2,397
2023 MIPS performance period (excludes QPs) Adjusted **for MVP. (c) = (a) – (b)**	0	10,**278**	7,**296**	17,**574**
*Currently approved 2023 MIPS performance period (excludes QPs) (d)	0	10,434	7,372	17,806
Difference (**e**) = (**d**) - (**c**)	0	**-156**	**-76**	**--232**

*Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a

clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group TINs could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. we refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 through 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2023 performance period/2025 MIPS payment year, we are proposing a measure set of 194 quality measures. The new MIPS quality measures finalized for inclusion in MIPS for the CY 2023 performance period/2025 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures finalized for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 107, as well as proposed counts of new, removed, and substantively changed measures.

TABLE 107: Summary of Quality Measures Proposed for the CY 2023 Performance Period/2025 MIPS Payment Year

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal*	# Measures Proposed with a Substantive Change*	# Measures Proposed for CY 2023*
Medicare Part B Claims	0	-5	15	29
MIPS CQMs Specifications	+8	-14	56	168
eCQM Specifications	+1	-2	42	47
Survey – CSV	0	0	1	1
Administrative Claims	+1	0	0	4
Total*	+9	-15**	75	194

*A measure may be specified under multiple collection types but will only be counted once in the total.
**We are proposing to remove 15 MIPS quality measures and partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs.

For the CY 2023 performance period/2025 MIPS payment year, we are proposing a net reduction of 6 quality measures across all collection types compared to the 200 measures finalized for the CY 2022 performance period/2024 MIPS payment year (86 FR 65542). Specifically, as discussed in section IV.A.10.c.(1)(c) of this rule, we are proposing to add 9 new MIPS quality measures, remove 15 MIPS quality measures, partially remove 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs, and make substantive updates to 75 MIPS quality measures. We do not anticipate that our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures. We refer readers to section V.B.9.e.(7) of this proposed rule for the proposed change in associated burden related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year.

(3) Quality Payment Program Identity Management Application Process

This rule is not proposing any new or revised collection of information requirements or burden related to the identity management application process. We are proposing to adjust the number of respondents based on updated data. The proposed requirements and burden will be submitted to OMB under control number 0938–1314 (CMS–10621).

Based on historical trends for the number of eligible clinicians, groups, or third parties that register for new accounts, we noticed that we inadvertently underestimated our assumptions in the CY 2022 PFS final rule (86 FR 65582). In order to accurately capture the incremental change in the number of respondents in previous years, we are using a rolling average of the number of respondents that would register for obtaining new accounts. Therefore, we are proposing to adjust our estimates from 3,741 to 6,500 for the number of respondents that would submit their information to obtain new user accounts in the HARP system for the CY 2023 performance period/2025 MIPS payment year. This would result in an increase of 2,759 respondents. We are not proposing to adjust the currently approved estimated time of 1 hour per respondent to obtain a new account. As shown in Table 108, it would take 1 hour at $98.28/hr for a computer systems analyst (or their equivalent) to obtain an account for the

HARP system. In aggregate we estimate an annual burden of 6,500 hours (6,500 registrations × 1 hr/registration) at a cost of $638,820 (6,500 hrs × $98.28/hr).

TABLE 108: Estimated Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Description	Burden Estimate
# of New Users completing the Identity Management Application Process (a)	6,500
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a)*(b)	**6,500**
Cost Per Application @ computer systems analyst's labor rate of $95.22/hr.) (d)	$98.28
Total Annual Cost for completing the Identity Management Application Process (e) = (a)*(d)	**$638,820**

As shown in Table 109, using the unchanged currently approved hours per respondent burden estimate, the proposed increase of 2,759 respondents from 3,741 to 6,500 for the CY 2023 performance period/2025 MIPS payment year would result in an estimated increase of 2,759 hours (+2.759 respondents × 1hr/respondent) at a cost of $271,155 (2,759 hrs × 98.28/hr).

TABLE 109: Estimated Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	3,741
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (See Table 108, row (c)) (b)	6,500
Difference (c) = (b) – (a)	**+2,759**
Total Currently Approved Annual Cost (d)	$367,665
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (See Table 108, row (e)) (e)	$638,820
Difference (f) = (e) – (d)	**+271,155**

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not proposing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are proposing to adjust our currently approved burden estimates based on our changes in assumptions for calculating the data. We refer readers to Table 118 of this section for the proposed change in associated burden related to the submission of Medicare Part B claims data for the MVP quality performance category in the CY 2023 performance period/2025 MIPS payment year.

The following proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912), the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60004 through 60005, 84 FR 63124 through 63126, 85 FR 84975 through 84976 and 86 FR 65582 through 65584) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 105, based on data from the CY 2019 performance period/2021 MIPS payment year, we estimate that 27,006 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. In this rule, we are proposing to adjust the number of Medicare Part B claims respondents from the currently approved estimate of 25,427 to 27,006 (an increase of 1,579).

As shown in Table 105, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) for a computer systems analyst at a cost of $14.74 (0.15 hr x $98.28/hr) to 7.2 hours for a computer systems analyst at a cost of $707.61 (7.2 hr x $98.28/hr). We assume that the burden will involve becoming familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $115.22/hr for a medical and health services manager, 1 hour at $259.98/hr for a physician, 1 hour at $49.86/hr for an LPN, 1 hour at $98.28/hr for a computer systems analyst, and 1 hour at $41.10/hr for a billing and posting clerk. We are not proposing to revise our currently approved per response time estimates.

As shown in Table 110, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a

maximum of 14.2 hours (7.2 hr + 7 hr). In aggregate, the total annual time for the CY 2023 performance period/2025 MIPS payment year ranges from 193,093 hours (7.15 hr x 27,006 clinicians) to 383,485 hours (14.2 hr x 27,006 clinicians). The estimated annual cost (per clinician) ranges from $809.62 [(0.15 hr x $98.28/hr) + (3 hr x $115.22/hr) + (1 hr x $98.28/hr) + (1 hr x $49.86/hr) + (1 hr x $41.10/hr) + (1 hr x $259.98/hr)] to a maximum of $1,502.49 [(7.2 hr x $98.28/hr) + (3 hr x $115.22/hr) + (1 hr x $98.28/hr) + (1 hr x $49.86/hr) + (1 hr x $41.10/hr) + (1 hr x $259.98/hr)]. The total annual cost for the CY 2023 performance period/2025 MIPS payment year ranges from a minimum of $21,864,598 (27,006 clinicians x $810) to a maximum of $40,576,245 (27,006 clinicians x $1,502.49).

TABLE 110: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	27,006	27,006	27,006
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	**193,093**	**217,398**	**383,485**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr @ varying times) (j)	$14.74	$103.19	$707.61
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr @ 3 hr) (k)	$345.66	$345.66	$345.66
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr @ 1 hr) (l)	$98.28	$98.28	$98.28
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr @1 hr) (m)	$49.86	$49.86	$49.86
Cost to Review Measure Specifications (@ billing clerk's labor rate of $41.10/hr @ 1 hr) (n)	$41.10	$41.10	$41.10
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr @ 1 hr) (o)	$259.98	$259.98	$259.98
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$809.62	$898.07	$1,502.49
*Total Annual Cost (q) = (a) * (p)	$21,**864,598**	$**24,253,278**	$40,**576,245**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 111, using our unchanged currently approved burden per response estimates, the increase in number of respondents from 25,427 to 27,006 results in a total maximum adjustment of 22,422 hours (+1,579 respondents x 14.2 hr/respondent) at a cost of $2,372,432 (+1,579 respondents x $1,502.49/respondent). For purposes of calculating total burden associated with this proposed rule as shown in Tables 132, 133, and 135, only the maximum burden is used.

TABLE 111: Adjusted Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	361,063
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (see Table 110, row (i))	383,485
Difference (c) = (b) - (a)	**+22,422**
Total Currently Approved Annual Cost (d)	$38,203,813
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (see Table 110, row (q)	$40,576,245
Difference (f) = (e) - (d)	**+$2,372,432**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 through 77505 and 82 FR 53912 through 53914), the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60005 through 60006, 84 FR 63127 through 63128, 85 FR 84977 through 84979, and 86 FR 65584 through 65586) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 118 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2023 performance period/2025 MIPS payment year.

As noted in Tables 105 and 106, based on data from the CY 2019 performance period/2021 MIPS payment year, for the CY 2023 performance period/2025 MIPS payment year, we assume that 47,584 clinicians (37,306 individuals and 10,278 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is an increase of 850 individuals and a decrease of 156 groups from the estimates of 36,456 individuals and the 10,434 groups provided in the CY 2022 PFS final rule (86 FR 65585). Given that the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data is total of 9 hours at a cost of $982.65 per response. This consists of 3 hours at $98.28/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $115.22/hr for a medical and health services manager, 1 hour at $98.28/hr for a computer systems analyst, 1 hour at $49.86/hr for a LPN, 1 hour at $41.10/hr for a billing clerk, and 1 hour at $259.98/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) at $98.28/hr for a computer systems analyst at a cost of $8.15 (0.083 hr x $98.28/hr). Overall, we estimate 9.083 hrs/response (3 hrs + 2 hrs + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hrs) at a cost of $982.65/response [(3 hrs × $98.28/hr) + (2 hrs × $115.22/hr) + (1 hr × $259.98/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr) + (0.083 hrs × $98.28/hr)].

As shown in Table 112, For the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 432,205 hours [9.083 hrs/response × (37,306 clinicians submitting as individuals + 10,278 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians, a total of 47,584 responses)] at a cost of $46,758,418 (47,584 responses × $982.65/response).

TABLE 112: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	37,306
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,278
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	**47,584**
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)*(k)	**432,205**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr) (m)	$294.84
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (n)	$230.44
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (o)	$98.28
Cost LPN Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (p)	$49.86
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $41.10/hr) (q)	$41.10
Cost Physician Review Measure Specifications (@ physician's labor rate of $259.98/hr) (r)	$259.98
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $98.28/hr) (s)	$8.15
*Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$982.65
***Total Annual Cost (u) = (c) * (t)**	**$46,758,418***

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 113, using the unchanged currently approved hours per respondent burden estimate, the increase of 694 respondents from 46,890 to 47,584 for the CY 2023 performance period/2025 MIPS payment year results in an increase of 6,303 hours (+694 respondents × 9.083 hr/respondent) and $681,959 (694 respondents × $982.65/respondent).

TABLE 113: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	425,902
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (see Table 112, row (l))	432,205
Difference (c) = (b) - (a)	**+6,303**
Total Currently Approved Annual Cost (d)	$46,076,459
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (see Table 112, row (u))	$46,758,418
Difference (f) = (e) - (d)	**+$681,959**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130) and the CY 2021 PFS final rule (85 FR 84979 through 84980) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 118 of this section.

Based on CY 2019 performance period/2021 MIPS payment year data, for the CY 2023 performance period/2025 MIPS payment year, we assume that 45,760 clinicians (38,464 individual clinicians and 7,296 groups and virtual groups) would submit quality data using the eCQM collection type. This is an increase of 2,063 individuals and a decrease of 76 groups from the estimates of 36,401 individuals and 7,372 groups provided in the CY 2021 PFS final rule (85 FR 84979). We assume the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $98.28/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $115.22/hr for a medical and health services manager, 1 hour at $259.98/hr for a physician, 1 hour at $98.28/hr for a computer systems analyst, 1 hour at $49.86/hr for an LPN, and 1 hour at $41.10/hr for a billing clerk. Overall, we estimate a cost of $876.22/response [(2 hr × $98.28/hr) + (2 hr × $115.22/hr) + (1 hr × $259.98/hr) + (1 hr × $98.28/hr) + (1 hr × $49.86/hr) + (1 hr × $41.10/hr)].

As shown in Table 114, For the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 366,080 hours [8 hr × 45,760 (38,464 clinicians + 7,296 groups and virtual groups)] at a cost of $40,095,827 (45,760 responses × $876.22/response).

TABLE 114: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	38,464
# of Groups submitting via EHR on behalf of individual clinicians (b)	7,296
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	**45,760**
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	**366,080**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr) (l)	$196.56
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (m)	$230.44
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (n)	$98.28
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (o)	$49.86
Cost to Review Measure Specifications (@ clerk's labor rate of $41.10/hr) (p)	$41.10
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr) (q)	$259.98
*Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$876.22
***Total Annual Cost (s) = (c) * (r)**	**$40,095,827**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 115, using the unchanged currently approved hours per respondent burden estimate, the proposed increase of 1,987 respondents from 43,773 to 45,760 for the CY 2023 performance period/2025 MIPS payment year results in an increase of 15,896 hours (+1,987 respondents × 8 hr/respondent) at a cost of $1,741,049 (+1,987 respondents × $876.22/respondent).

TABLE 115: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	350,184
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (see Table 114, row (k))	366,080
Difference (c) = (b) - (a)	**+15,896**
Total Currently Approved Annual Cost (d)	$38,354,778
Total Annual Cost for Respondents in CY 2022 PFS proposed rule (e) (see Table 114, row (s))	$40,095,827
Difference (f) = (e) - (d)	**+1,741,049**

(7) ICRs Regarding Burden for MVP Reporting

The proposed requirements and burden associated with the implementation of MVPs and subgroups will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(a) Burden for MVP Reporting Requirements

We refer readers to the CY 2022 PFS final rule (86 FR 65588 through 65592) for our previously finalized burden and requirements for submission of data for the MVP quality performance category. In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate

through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 PFS final rule for our previously finalized assumptions on the estimated number of clinicians participating as subgroups in the CY 2023 performance period/2025 MIPS payment year (86 FR 65589).

For the ICRs related to MVP participants, we continue to use the MIPS submission data from the CY 2019 performance period/2021 MIPS payment year. In Appendix 3: MVP Inventory of this rule, we propose to revise 6 of the 7 MVPs finalized in Appendix 3: MVP Inventory of the CY 2022 PFS final rule (86 FR 65998 through 66031). Specifically, these revisions are based on the proposed removal of certain improvement activities in section IV.A.10.c.(3)(b)(ii) of this rule, the addition of other relevant existing quality measures for MVP participants to select from and the proposed addition of the ONC direct review attestation requirement in the Promoting Interoperability performance category to all previously finalized MVPs. Additionally, we propose 5 new MVPs for the CY 2023 performance period/2025 MIPS payment year. If the proposed 5 new MVPs are finalized, MVP participants would have a total of 12 MVPs available for the CY 2023 performance period/2025 MIPS payment year. Due to the availability of new MVPs and addition of relevant quality measures to existing MVPs, we expect an increase in the number of MVP participants. Therefore, we estimate that 12 percent of the clinicians would participate in MVP reporting in the CY 2023 performance period/2025 MIPS payment year. This is an increase of 2 percentage points from the currently approved estimate of 10 percent in the CY 2022 PFS final rule (86 FR 65588 through 65589).

We assume that the changes to the existing MVPs and the addition of new MVPs would not impact the currently approved number of subgroups. We expect that clinician participation in subgroups will be relatively low for the CY 2023 performance period/2025 MIPS payment year due the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we are not proposing any adjustments to our previously finalized assumption in the CY 2022 PFS final rule (86 FR 65589) of 20 subgroups that would participate in MVP reporting.

In section IV.A.8.e.(4)(b) of this rule, we propose to modify § 414.1365(d)(3)(i)(A)(*1*) to read that subgroups are scored on each selected population health measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We also propose to add § 414.1365(d)(3)(i)(B)(*1*) so that subgroups are scored on each selected outcomes-based administrative claims measure based on their affiliated group score, if available, and that if the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points. We assume that these proposals are related to the subgroup scoring of administrative claim measures and do not impact clinician participation in subgroups. Furthermore, clinicians do not submit data for the administrative claims' measures and hence, there is no associated burden relevant to these measures for clinicians participating as subgroups. Therefore, we are not proposing any adjustments to our previously finalized assumptions for subgroup reporting burden of the MVP quality performance category in the CY 2022 PFS final rule (86 FR 65592).

Additionally, in section IV.A.8.e.(4)(c) of this rule, we propose at § 414.1318(b)(1) that we will not assign a score for a subgroup that registers and does not submit data for the applicable performance period. We also propose to make conforming changes at § 414.1318(b) to state that, except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment. We assume that subgroups that register for MVP reporting intend to submit data for the measures and activities in an MVP. These proposed policies are meant to clarify the scoring for subgroups in instances when a subgroup does not submit data as originally intended when registering as a subgroup. Therefore, we are not proposing any adjustments to our previously finalized assumptions for subgroup reporting burden of the MVP quality performance category in the CY 2022 PFS final rule (86 FR 65592).

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2022 PFS final rule (86 FR 65589 through 65590) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

As shown in Table 116, consistent with our previously finalized assumptions in the CY 2022 PFS final rule (86 FR 65590), we estimate that the registration process for clinicians choosing to submit MIPS data for the measures and the activities in an MVP would require 0.25 hours of a computer systems analyst's time for the CY 2023 performance period/2025 MIPS payment year. We assume that the staff involved in the MVP registration process will mainly be computer systems analysts or their equivalent, who have an average labor cost of $98.28/hour.

As discussed above, based on data from the CY 2019 performance period/2021 MIPS payment year, the proposed changes to existing MVPs and the addition of new MVPs, we estimate that approximately 12 percent of the clinicians that currently participate in MIPS would submit data for the measures and activities in an MVP. For the CY 2023 performance period/2025 MIPS payment year, we assume that we would receive a total of 16,432 submissions for the measures and activities included in MVPs. This total includes our estimate of 20 subgroup reporters that would also be reporting MVPs in addition to MVP reporters who currently participate in traditional MIPS. Therefore, we assume that the total number of individual clinicians, groups, subgroups and APM Entities to complete the MVP registration process is 16,432. As shown in Table 116, we estimate that it would take 4,108 hours (16,432 respondents × 0.25 hr/respondent) at a cost of $403,734 (4,108 hrs × 98.28/hr) for individual clinicians, groups and APM Entities to register for MVPs in the CY 2023 performance period/2025 MIPS payment year.

TABLE 116: Total Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	16,432
Estimated Total Annual Burden Hours Per Registration (b)	0.25
Estimated Total Annual Burden Hours for MVP Registration (c) = (a) * (b)	**4,108***
Estimated Cost Per MVP (@ computer systems analyst's labor rate of $98.28/hr. (d)	98.28
Estimated Total Annual Burden Cost for MVP Registration (e) = (c) * (d)	**$403,734***

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

As shown in Table 117, for the CY 2023 performance period/2025 MIPS payment year, the proposed adjustment in the number of respondents expected to register for MVP reporting from 12,917 to 16,432 results in an increase of 3,515 respondents. In aggregate, when combined with the unchanged hourly burden per respondent, this would result in an increase of 879 hours (+3,515 respondents × 0.25 hr/respondent) at a cost of $86,388 (879 hrs × 98.28/hr).

TABLE 117: Change in Estimated Burden for MVP Registration: Individuals, Groups, and APM Entities

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	3,229
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 116, row (c))	4,108
Difference (c) = (b) - (a)	**+879**
Total Currently Approved Annual Cost (d)	$317,346
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 116, row (e))	$403,734
Difference (f) = (e) - (d)	**+86,388**

(ii) Burden for Subgroup Registration

We previously established at § 414.1365(b) a registration process for clinicians who choose to report MVPs through a subgroup. We refer readers to the CY 2022 PFS final rule for our previously finalized burden relevant to subgroup registration for clinicians participating in MVP reporting (86 FR 65590).

In section IV.A.8.e.(2) of this rule, we propose to modify the definition of a single specialty group at § 414.1305 to state that single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims. We also propose to modify the definition of a multispecialty group at § 414.1305 to state that multispecialty group means a group that consists of two or more specialty types as determined by CMS using Medicare Part B claims. We believe that these definitions would help groups understand their specialty determination. However, we are not proposing any adjustments to the subgroups burden associated with these proposals because we believe that these definitions would not impact the utilization of subgroups by groups and hence, would not change the way groups choose to organize clinicians in subgroups.

In section IV.A.8.e.(3)(b) of this rule, we propose that as part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. Under this proposed policy, we would identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text—only field, if the options we provide do not correctly describe the subgroup. We assume that the burden associated with choosing a key scenario would minimize the time required for subgroups to provide a narrative description. Additionally, we anticipate the narratives to be short descriptions of the nature of a group practice and appropriately reflect the subgroup composition. Therefore, we are not proposing any adjustments in the burden for subgroup registration because we assume that the narrative requirement would not add significant burden to the currently approved half an hour for subgroup registration in the CY 2022 PFS final rule (86 FR 65590). We refer readers to section IV.A.8.e.(3)(b) of this rule for examples of the subgroup narrative description.

In section IV.A.8.f.(3)(d) of this rule, we are proposing to add at § 414.1318(a)(4) that CMS will apply the low-volume threshold criteria for a subgroup as described under § 414.1318(a)(1) using information from the initial 12-month segment of the applicable MIPS determination period. Additionally, we propose to make conforming changes at § 414.1318(a)(1) to state that, except as provided under paragraph (a)(2) of this section and subject to (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and

414.1310. We assume that these proposals would provide clarification for groups to identify their eligibility to form subgroups and also ensure that an individual eligible clinician or group will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. This proposal does not change the application of low-volume threshold and special status as described under § 414.1318(a)(1) for clinicians in subgroups. Therefore, we are not proposing any adjustments to the currently approved burden for subgroup registration.

In section IV.A.8.e.(3)(c) of this rule, we propose at § 414.1318(a)(3) that an individual eligible clinician, as represented by a TIN–NPI combination may register for no more than one subgroup within a group's TIN. We assume that the proposal would limit the number of subgroups that a clinician could participate under a TIN and would not result in additional burden for clinicians to participate as subgroups. Therefore, we are not proposing any adjustments to the currently approved burden for subgroup registration.

Therefore, we are not prosing any changes to our previously finalized assumptions for subgroup registration burden. The burden relevant to subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the ICR for subgroup registration under that control number. Similar to our assumptions in the CY 2022 PFS final rule, we continue to capture the burden associated with subgroup quality reporting in the ICR for MVP quality performance category submission. The burden associated with subgroup submissions for Promoting Interoperability and improvement activities is included in the relevant ICRs in sections V.B.9.g.(3) and V.B.9.i. of this rule.

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we previously finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). As discussed in section IV.A.8.b. of this rule, we are not proposing new requirements to submit data for the quality performance category of MVPs. Therefore, we are not proposing any changes to our currently approved hourly burden per respondent estimates for submitting the MVP quality performance category data.

As described above in this section of the proposed rule, we estimate that 12 percent of the clinicians who participated in MIPS for the CY 2019 performance period/2021 MIPS payment year would submit data for the quality performance category of MVP in the CY 2023 performance period/2025 MIPS payment year. We also estimate that there would be 20 subgroups reporters in the CY 2023 performance period/2025 MIPS payment year. As shown in Table 118, we estimate that 6,240 clinicians and 10 subgroups would submit data using eCQMs collection type; 6,849 clinicians and 10 subgroups would submit data using MIPS CQM and QCDR collection type; and 3,683 clinicians and 0 subgroups would submit data for the MVP quality performance category using the Medicare Part B claims collection type. For the CY 2023 performance period/2025 MIPS payment year, using our unchanged hourly burden per respondent estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 33,125 hours [5.3 hr × 6,250 (6,240 +10) respondents] at a cost of $3,627,750 (6,250 respondents × 580.44/respondent) for the eCQM collection type, 38,799 hours [5.97 hr × 6,499 (6,489 +10)] at a cost of $4,200,239 (6,499 respondents × 646.29/respondent) for the MIPS CQM and QCDR collection type, and 34,768 hours (9.44 hr × 3,683 clinicians) at a cost of $3,678,102 (3,863 respondents × 998.67/respondent) for the Medicare Part B claims collection type.

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TABLE 118: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	6,240	6,489	3,683
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	6,250	6,499	3,683
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**33,125**	**38,799**	**34,768**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $98.28/hr @ varying times) (k)	$130.71	$196.56	$471.74
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $115.22/hr) (l)	$153.24	$153.24	$230.44
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $98.28/hr) (m)	$64.87	$64.87	$64.87
Cost to Review Measure Specifications (@ LPN's labor rate of $49.86/hr) (n)	$32.91	$32.91	$32.91
Cost to Review Measure Specifications (@ billing clerk's labor rate of $41.10/hr) (o)	$27.12	$27.12	$27.12
Cost to Review Measure Specifications (@ physician's labor rate of $259.98/hr) (p)	$171.59	$171.59	$171.59
*Total Annual Cost Per Clinician (q) = (k) + (l) + (m) + (n) + (o) + (p)	$580.44	$646.29	$998.67
***Total Annual Cost (r) = (c) * (q)**	**$3,627,750**	**$4,200,239**	**$3,678,102**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

Table 119 illustrates the proposed changes in estimated burden for clinicians who would submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and claims collection types in the CY 2023 performance period/2025 MIPS payment year. In aggregate, when combined with the unchanged hourly burden per respondent, the increase in 3,515 respondents that would submit data for the MVP quality performance category would result in an increase of 7,303 hours at a cost of $799,845 for the eCQM collection type, an increase of 7,636 hours at a cost of $826,605 for the CQM and QCDR collection type, and an increase of 8,080 hours at a cost of $856,859 for the claims collection type.

TABLE 119: Change in Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	25,822	31,163	26,688
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 118, row (k))	33,125	38,799	34,768
Difference (c) = (b) - (a)	**+7,303**	**+7,636**	**+8,080**
Total Currently Approved Annual Cost (d)	$2,827,905	$3,373,634	$2,821,243
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 118, row (r))	$3,627,750	$4,200,239	$3,678,102
Difference (f) = (e) - (d	**+799,845**	**+826,605**	**+856,859**

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(8) Beneficiary Responses to CAHPS for MIPS Survey

This rule is not proposing any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes to the CAHPS for MIPS Survey process under that control number.

(9) Group Registration for CAHPS for MIPS Survey

This rule is not proposing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes to the CAHPS for MIPS Survey registration process under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. The requirements and the associated burden are currently approved under OMB control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the call for MIPS quality measures process under that control number.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2023 performance period/2025 MIPS payment year, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis, and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The proposed requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), and the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60011 through 60012, 84 FR 63134 through 63135, 85 FR 84984 through 84985, and 86 FR 65596 through 65598) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

In section IV.A.10.c.(4)(m)(i) of this rule, we are proposing not to continue the reweighting policy at § 414.1380(c)(2)(i)(A)(*4*)(*ii*) to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score for NPs, PAs, CRNAs, and CNSs for the CY 2023 performance period/2025 MIPS payment year. If we adopt this proposal as final policy, some of these types of clinicians who are automatically assigned a weight of zero percent for the Promoting Interoperability performance category under our current policy may choose to submit an application for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship or as a result of a decertification of an EHR. Based on historically low participation trends for NPs, PAs, CRNAs, and CNSs that

submitted data individually for the Promoting Interoperability performance category for prior performance periods, we are unable to estimate how many of these clinicians would be applying for reweighting the Promoting Interoperability performance category to zero percent. Therefore, we are not proposing any adjustments to the number of respondents submitting reweighting applications.

In section IV.A.10.c.(4)(m)(ii) of this rule, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals only for the CY 2023 performance period/2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)(*4)(i)* to reflect the proposal. We are also proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year and to revise § 414.1380(c)(2)(i)(A)(*4*)(*iii*) to reflect the proposal. We are not proposing any adjustments to the number of respondents submitting reweighting applications due to these proposals because it does not change the existing reweighting policy for these clinician types participating in MIPS in the CY 2023 performance period/2025 MIPS payment year.

Table 120 summarizes the burden for clinicians to apply for reweighting of the Promoting Interoperability performance category to zero percent due to a significant hardship or as a result of a decertification of an EHR. Based on the number of reweighting applications received by March 31, 2022 for the CY 2021 performance period/ 2023 MIPS payment year, we estimate that we would receive a total of 31,135 reweighting applications for the CY 2023 performance period/2025 MIPS payment year. Out of the 31,135, we estimate that 13,480 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. We estimate that the remaining 17,655 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. As discussed in section V.B.9.a.(4) of this rule, we assume ACO APM Entities will submit data through the APP and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual, group, or at the APM Entity level. Based on the actual number of APM Entities that submitted reweighting applications for the CY 2021 performance period/2023 MIPS payment year, we estimate that 20 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2023 performance period/2024 MIPS payment year. This is a decrease of 10 from the currently approved estimate of 30 APM entities that would submit a reweighting application. Combined with our aforementioned estimate of 31,135 eligible clinicians and groups, the total estimated number of respondents expected to submit applications for reweighting of the Promoting Interoperability and other performance categories for the CY 2023 performance period/2025 MIPS payment year is 31,155. This proposed adjustment results in a decrease of 11,672 respondents compared to our currently approved estimate of 42,827 respondents (86 FR 65597). This decrease is based on the actual number of reweighting applications submitted for the CY 2021 performance period/ 2023 MIPS payment year. Similar to the data used to estimate the number of respondents in the CY 2021 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. We want to note that our respondent estimate also includes the reweighting applications submitted during the extended period ending March 31, 2022, due to the PHE for COVID–19.

Consistent with our assumptions in the CY 2022 PFS final rule (86 FR 65596 through 65598), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the application. As shown in Table 120, we estimate an annual burden of 7,789 hours (31,155 applications × 0.25 hr/ application) and $765,503 (7,789 hours × $98.28/hr).

TABLE 120: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	31,135
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	20
Total Applications Submitted (c)	**31,155**
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	**7,789**
Labor Rate for a computer systems analyst (f)	$98.28/hr
Total Annual Cost (g) = (e) * (f)	**$765,503**

The proposed adjustment in the estimated number of respondents, from 42,827 to 31,155 respondents, results in a decrease of 11,672 respondents. In aggregate, using the unchanged currently approved hourly burden per

response estimate, as shown in Table 121, the decrease in 11,672 respondents would result in a decrease of 2,918 hours (−11,672 respondents × 0.25 hr/respondent) at a cost of $286,781 (−2,918 hrs × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 121: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2022 PFS final rule (a)	10,707
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 120, row (c))	7,789
Difference (c) = (b) - (a)	**-2,918**
Total Currently Approved Annual Cost in CY 2022 PFS final rule (d)	$1,052,284
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 120, row (e))	$765,503
Difference (f) = (e) - (d)	**-$286,781**

(3) Submitting Promoting Interoperability Data

The proposed requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, 82 FR 53919 through 53920), and the CY 2019, CY 2020, CY 2021 and CY 2022 PFS final rules (83 FR 60013 through 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, 86 FR 65598 through 65600) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In section IV.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule, we are proposing to require MIPS eligible clinicians to report the Query of PDMP measure (which requires reporting a ''yes/no'' response) for the Promoting Interoperability performance category. If this proposal is finalized, we are proposing two exclusions beginning with the performance period in CY 2023: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, and. (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. Due to lack of sufficient data regarding the number of clinicians who voluntarily submitted data for optional measures in the Promoting Interoperability performance category, we have consistently been unable to estimate the associated burden for the reporting of such measures. Therefore, we are not proposing to adjust our currently approved time required for clinicians to submit data for the Promoting Interoperability performance category because we are unable to account for any change in burden due to the proposed change to require the currently optional Query of PDMP measure.

In section IV.A.10.c.(4)(e) of this rule, we are proposing to add an additional measure through which a MIPS eligible clinician could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we are proposing to add the following new measure to the Health Information Exchange Objective beginning with the performance period in CY 2023: Enabling Exchange Under TEFCA measure. We propose MIPS eligible clinicians would have three reporting options for the Health Information Exchange Objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable); (2) report on the HIE Bi-Directional Exchange measure; or (3) report on the proposed Enabling Exchange Under TEFCA measure. We believe that given the alignment between the Enabling Exchange under TEFCA measure and the existing HIE Bi-Directional exchange measure, adding this measure offers clinicians more opportunities to earn credit for the Health Information Exchange Objective. Because the proposed addition of Enabling Exchange Under TEFCA measure is optional for the Health Information Exchange Objective, we are unable to estimate the number of clinicians that would report this measure. Therefore, we are not proposing to adjust our currently approved time required for clinicians to submit data for the Promoting Interoperability performance category because we are unable to account for any change in burden due to the proposed change.

In section IV.A.10.c.(4)(f)(ii) of this rule, we propose revisions to the three active engagement options. Specifically, we propose to consolidate current options 1 and 2 into one option beginning with the performance period in CY 2023. Additionally, for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures a MIPS eligible clinician chooses to report, we propose to require MIPS eligible clinicians to submit their level of active engagement, either Pre-production and Validation or Validated Data Production (as proposed in section IV.A.10.c.(4)(f)(ii)(C) of this proposed rule), for each measure they report beginning with the performance period in CY 2023. If the proposed requirement for MIPS eligible clinicians to submit their level of active engagement with each measure is finalized, we estimate that it would add an additional one minute to the currently approved estimated time of 2.69 hours, resulting in a total estimated time of 2.71 hours, for clinicians to submit data for the Promoting Interoperability performance category.

In section IV.A.10.c.(4)(f)(ii)(D) of this rule, we also propose that beginning with the performance period in CY 2023, that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level in the next performance period for which they

report a particular measure. We refer readers to sections IV.A.10.c.4.(d) and IV.A.10.c.(4)(g) of this rule for additional information on proposed measure descriptions and changes to scoring methodologies in the Promoting Interoperability performance category.

As shown in Table 122, based on data from the CY 2019 performance period/2021 MIPS payment year, we estimate that a total of 54,770 respondents consisting of 43,117 individual MIPS eligible clinicians, 11,633 groups and virtual groups and 20 subgroups would submit Promoting Interoperability data in the CY 2023 performance period/2025 MIPS payment year. We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APP. As a result, we do not anticipate any change in burden for APM Participants submitting data for the Promoting Interoperability performance category. In section IV.A.10.c.(5)(b) of this rule, we are proposing to introduce a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year. Because the proposed reporting of the Promoting Interoperability performance category is voluntary, we are unable to estimate the number of APM Entities that would submit data on behalf of their clinicians for this category. Therefore, we assume that each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants.

TABLE 122: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data

Burden and Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability in CY 2023 (a)	43,117
Number of groups to submit Promoting Interoperability in CY 2023 (b)	11,633
# of Subgroups to submit Promoting Interoperability in MVPs during the CY 2023 MIPS performance period (c)	20
Total Respondents in **2023 MIPS** performance period (CY 2022 PFS Final Rule) (**d**) = (a) + (b) + **(c)**	**54,770**
Currently Approved Respondents in 2023 MIPS performance period (e)	51,667
Difference **(f)** = (d) – **(e)**	**+3,103**

As shown in Table 123, accounting for the change in hourly burden per respondent due to the proposed requirement for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective, the proposed increase in the number of respondents from 51,667 to 54,770 would result in a total burden of 148,427 hours (54,770 respondents × 2.71 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $14,587,406 (148,427 hrs × $98.28/hr)).

TABLE 123: Estimated Burden for Promoting Interoperability Performance Category Data Submission in CY 2023

Burden and Respondent Description	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	43,117
Number of groups to submit Promoting Interoperability (b)	11,633
Number of subgroups to submit Promoting Interoperability (c)	20
Total **(d)** = (a) + **(b)** + **(c)**	**54,770**
Total Annual Hours Per Respondent (e)	2.71
Total Annual **Hours (f)** = (d) *** (e)**	**148,427**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (g)	$98.28/hr
Total Annual Cost (h) = **(f) * (g)**	**$14,587,406**

As shown in Table 124, using our unchanged hourly burden per respondent estimate, the proposed increase in the number of respondents results in an increase of 9,443 hours (+3,103 respondents × 2.71 hrs + 51,667

× 0.02 hrs) at a cost of $928,058 (+9,443 hours × $98.28/hour).

TABLE 124: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	138,984
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (see Table 123, row (f))	148,427
Difference (c) = (b) - (a)	**+9,443**
Total Currently Approved Annual Cost (d)	$13,659,348
Total Annual Cost for Respondents in CY 2022 PFS proposed rule (e) (see Table 123, row (h))	$14,587,406
Difference (f) = (e) - (d)	**+$928,058**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the process for nomination of Promoting Interoperability measures under that control number.

i. ICR Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.10.c.(3)(b)(ii) of this rule, we are proposing changes to the improvement activities Inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding 4 new improvement activities; modifying 5 existing improvement activities; and removing 6 previously adopted improvement activities. We do not believe the changes to the improvement activities inventory will impact the estimated time required for interested parties to submit information, because MIPS eligible clinicians are still required to submit the same number of activities and the estimated time per response time for each activity is uniform. Therefore, we are not proposing to adjust our currently estimated time of 5 minutes or 0.083 hours (per response) for improvement activities submission.

We are proposing to adjust our currently approved burden estimates based on more recent data. As represented in Table 125, based on data from the CY 2019 performance period/2021 MIPS payment year, we estimate that a total of 96,980 respondents consisting of 78,239 individual clinicians, 17,721 groups and 20 subgroups will submit improvement activities during the CY 2023 performance period/2025 MIPS payment year. This proposed adjustment represents an increase of 15,398 respondents (14,394 individuals, 4 groups and 0 subgroups) from the currently approved estimate of 81,582 respondents (63,845 individuals and 17,717 groups, and 20 subgroups) in the CY 2022 PFS final rule (86 FR 65603).

As discussed in sections V.B.9.e.(2) and V.B.9.g.(3) of this proposed rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we are proposing to update our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or participating in an ACO in the CY 2019 performance period/2021 MIPS payment year but will be QPs in the CY 2023 performance period/2025 MIPS payment year, and will therefore not be required to submit improvement activities data.

TABLE 125: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2023 MIPS performance period (a)	78,239
# of Groups to submit improvement activities on behalf of clinicians during the CY 2023 MIPS performance period (b)	17,721
# of Subgroups to submit improvement activities in MVPs during the CY 2023 MIPS performance period (c)	20
Total # of Respondents (Groups, **Subgroups,** Virtual Groups, and Individual Clinicians) to submit improvement activities data during the CY **2023** MIPS performance period (CY 2022 **PFS** Final Rule) (**d**) = (a) + (b) + **(c)**	**96,980**
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 MIPS performance period (CY 2022 PFS Final Rule) (e)	81,582
Difference (**f**) = (d) - **(e)**	+**15,398**

Consistent with the CY 2022 PFS final rule, we continue to estimate that the time required per response per individual or group is 5 minutes or 0.083 hours for a computer system analyst at a labor rate of $98.28/hr to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (86 FR 65603). As shown in Table 126, we estimate an annual burden of 8,049 hours (96,980 responses × 0.083 hr) at a cost of $791,056 (8,049 hrs × $98.28/hr)) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 126: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 performance period (a)	96,980
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) * (b)	**8,049**
Labor rate for a computer systems analyst to submit improvement activities (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$791,056**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 127, using our unchanged currently approved per respondent burden estimate, the proposed increase in the number of respondents results in an increase of 1,278 hours (+15,398 respondents × 0.083 hr/respondent) at a cost of $125,602 (1,278 hrs × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 127: Change in Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	6,771
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 126, row (c))	8,049
Difference (c) = (b) - (a)	**+1,278**
Total Currently Approved Annual Cost (d)	$665,454
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 126, row (e))	$791,056
Difference (f) = (e) - (d)	**+$125,602**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

This rule is not proposing any new or revised collection of information requirements or burden related to the nomination of improvement activities. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the nomination of improvement activities under that control number.

k. Nomination of MVPs

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2021 PFS and CY 2022 PFS final rules (85 FR 84990 through 84991 and 86 FR 65605) for our previously finalized requirements and burden for collection of information relevant to nomination of MVPs for inclusion in the Quality Payment Program.

In section IV.A.8.a. of this rule, we propose updates to the previously finalized policies for the MVP development and maintenance process in the CY 2021 and 2022 PFS final rules (85 FR 84849 through 84856 and 86 FR 65410). Specifically, we propose to modify the MVP development process such that we would evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we would post a draft version of the submitted candidate MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. Interested parties and general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determined changes should be made to the candidate MVP, we would not notify the interested party who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. We also propose to modify the MVP maintenance process such that interested parties and the general public would be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. If we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. If we decide to make any revisions to an established MVP based on the recommendations submitted, we would adopt such revisions through notice and comment rulemaking.

We anticipate that these proposed changes do not require additional steps being added to the information collection relevant to the MVP nomination process described in the CY 2021 PFS final rule (85 FR 84990 through 84991). Therefore, we are not making any changes to the currently approved estimated time of 12 hours (86 FR 65605) for interested parties to submit their MVP candidates utilizing a standard template. Additionally, we refer readers to section VI.E.16.e.(2)(a) of this proposed rule where we discuss our impact analysis for these proposals.

In this rule, we are proposing to adjust the number of respondents submitting MVP nominations from 25 to 20 based on more recent data. This proposed adjustment would result in a decrease of 5 from our currently approved estimate of 25 in the CY 2022 PFS final rule (86 FR 65605). As shown in Table 128, for the CY 2023 performance period/2025 MIPS payment year, we estimate that we would receive 20 MVP nominations and the estimated time required per respondent would be 12 hours. This would result in an estimated annual burden of 240 hours (20 nominations × 12 hr/nomination) at a cost of $41,550 (20 × [(7.2 hr × $115.22/hr) + (4.8 hr × $259.97/hr)]).

TABLE 128: Estimated Burden for Nomination of MVPs

Burden and Respondent Descriptions	Burden Estimate
# of Nominations of New MVPs (a)	20
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a) * (d)	**240**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $115.22/hr) (f)	$829.58
Cost to Nominate an MVP (@ physician's labor rate of $259.98/hr) (g)	$1,247.90
Total Annual Cost Per Respondent (h) = (f) + (g)	$2,077.48
Total Annual Cost (i) = (a) * (h)	**$41,550**

As shown in Table 129, using our unchanged currently approved burden per respondent estimate, the proposed decrease in the number of respondents submitting MVP nominations results in a total annual adjustment of −60 hours (−5 respondents × 12 hr/nomination) at a cost of −$10,387 (−5 × [(7.2 hr × $115.22/hr) + (4.8 hr × $259.97/hr)]) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 129: Change in Estimated Burden for Nomination of MVPs

Burden and Respondent Descriptions	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	300
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 128, row (d))	240
Difference (c) = (b) - (a)	**-60**
Total Currently Approved Annual Cost (d)	$51,937
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 128, row (i))	$41,550
Difference (f) = (e) - (d)	**-$10,387**

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not proposing any changes to this information collection under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule is not proposing any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we propose to adjust our currently approved burden estimates based on updated projections for the CY 2023 performance period/2025 MIPS payment year. The proposed adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 130, based on our predictive QP analysis for the 2023 QP performance period/2025 MIPS payment year, which accounts for historical response rates in the CY 2021 performance period/2023 MIPS payment year, we are proposing to revise our estimate that a total of 287 respondents (156 APM Entities and 131 individual eligible clinicians representing approximately 7,182 Partial QPs) would make the election to participate as a Partial QP in MIPS. This is an increase of 37 from the 250 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hrs) to make this election. In aggregate, we are proposing to revise our estimated annual burden to 72 hours (287 respondents × 0.25 hrs/election) and $7,076 (72 hrs × $98.28/hr).

TABLE 130: Estimated Burden for Partial QP Election

Burden and Respondent Description	Burden Estimate
# of respondents making Partial QP election (156 APM Entities, 131 eligible clinicians) (a)	287
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	**72**
Labor rate for computer systems analyst (d)	$98.28/hr
Total Annual Cost (e) = (c) * (d)	**$7,076**

As shown in Table 131, using our unchanged currently approved per respondent burden estimate (86 FR 65605), we propose that the increase in the number of Partial QP elections results in an adjustment of 9 hours (+37 respondents × 0.25 hr/election) at a cost of +$884 (+9 hr × $98.28/hr) for the CY 2023 performance period/2025 MIPS payment year.

TABLE 131: Change in Estimated Burden for Partial QP Election

Burden and Respondent Descriptions	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	63
Total Annual Hours for Respondents in CY 2023 PFS proposed rule (b) (See Table 130, row (c))	72
Difference (c) = (b) - (a)	**+9**
Total Currently Approved Annual Cost (d)	$6,192
Total Annual Cost for Respondents in CY 2023 PFS proposed rule (e) (See Table 130, row (e))	$7,076
Difference (f) = (e) - (d)	**+$884**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements related to the Payer-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Payer-Initiated process under that control number.

(2) Eligible Clinician-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements or burden related to the Eligible Clinician-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Eligible Clinician-Initiated Process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not proposing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden for the All-Payer Combination option are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

This rule is not proposing any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Compare Tools. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

p. Summary of Annual Quality Payment Program Burden Estimates

Table 132 summarizes this proposed rule's total burden estimates for the Quality Payment Program for the CY 2023 performance period/2025 MIPS payment year.

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In the CY 2022 PFS final rule, the total estimated burden for the CY 2023 performance period/2025 MIPS payment year was 1,383,049 hours at a cost of $139,501,770 (86 FR 65613). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2022 PFS final rule, the total estimated annual burden of continuing the policies and information collections set forth in the CY 2022 PFS final rule into the CY 2023 performance period/2025 MIPS payment year is 1,386,649 hours at a cost of $147,977,762. These represent an increase of 3,600 hours and an increase of $8,475,992. To understand the burden implications of the policies in

this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2022 PFS final rule into the CY 2023 performance period/2025 MIPS payment year. This burden estimate of 1,476,903 hours at a cost of $157,603,546 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, an increase of 90,254 hours and $9,625,784. This burden estimate is higher than the burden approved for information collection related to the CY 2022 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2023 performance period/2025 MIPS payment year is 1,465,864 hours and $156,389,613 which represents an increase of 79,215 hours and $8,411,851 from the CY 2022 PFS final rule. The difference of −11,039 hours (79,215 hours–90,254 hours) and −$1,213,933 ($8,411,851–$9,625,784) between this estimate and the total burden shown in Table 132 is the decrease in burden associated with impacts of the policies for the CY 2023 performance period/2025 MIPS payment year.

TABLE 132: Summary of Burden Estimates and Requirements from the CY 2023 PFS Proposed Rule

CY 2023 Performance Period/2025 MIPS Payment Year		
Burden Estimate Description	Time (Hours)	Cost
Currently approved burden in CY 2022 PFS final rule (a)	1,383,049	$139,501,770
CY 2022 PFS final rule w/ updated wage rates and ICRs (b)	1,386,649	$147,977,762
CY 2022 PFS final rule w/ updated data and assumptions (c)	1,476,903	$157,603,546
Change in burden due to updated data and assumptions (**d) = (c) – (b**)	+90,254	+$9,625,784
CY 2023 PFS proposed rule Total Burden (e)	1,465,864	$156,389,613
Total change in burden (as shown in Table 133) **(f) = (e) – (b**)	+79,215	+$8,411,851
Change in burden associated with policies (**g) = (f) – (d**)	-11,039	-$1,213,933

TABLE 133: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses	Responses	Change in Responses	Currently Approved Total Time (Hours)*	Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see section V.B.9.c.(2), Table 98)	84	90	6	1,176	1,035	-141
§ 414.1400 Registry self-nomination (see section V.B.9.c.(3), Table 99)	147	160	13	841	320	-521
§ 414.1400 Third Party Intermediary Plan Audits (see section V.B.9.c.(4), Table 102)	0	124	124	0	832	+832
Open Authorization (OAuth) Credentialing and Token Request Process (see section V.B.9.d., Table 104)	15	15	0	15	30	+15
Quality Payment Program Identity Management Application Process (see section V.B.9.e.(3), Table 109)	3,741	6,500	2759	3,741	6,500	+2,759
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims collection type (see section V.B.9.e.(4), Table 111)	25,427	27,006	1,579	361,063	383,485	+22,422
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.9.e.(5), Table 113)	46,890	47,584	694	425,902	432,205	+6,303
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.9.e.(6), Table 115)	43,773	45,760	1,987	350,184	366,080	+15,896
MVP Registration (see section V.B.9.e.(7)(a)(i), Table 117)	12,917	16,432	3,515	3,229	4,108	+879
MVP Quality Submission (see section V.B.9.e.(7)(a)(iii), Table 119)	12,917	16,432	3,515	83,673	106,692	+23,019
§ 414.1375 (Promoting Interoperability Performance	42,827	31,155	-11,672	10,707	7,789	-2,918

Requirement	Currently Approved Responses	Responses	Change in Responses	Currently Approved Total Time (Hours)*	Total Time (Hours)	Change in Total Time (Hours)
Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.9.g.(2), Table 121)						
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.9.g.(3), Table 124)	51,667	54,770	3,103	138,984	148,427	+9,443
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.9.i, Table 127)	81,582	96,980	15,398	6,771	8,049	+1,278
Nomination of MVPs (see section V.B.9.k, Table 129)	25	20	-5	300	240	-60
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.9.m, Table 131)	250	287	37	63	72	+9
TOTAL	**322,262**	**343,315**	**+21,053**	**1,386,649**	**1,465,864**	**+79,215**

Table 134 provides the reasons for proposed changes in the estimated burden for information collections in the Quality Payment Program segment of this rule. We have divided the reasons for our proposed change in burden into those related to proposed policies and those related to proposed adjustments in burden continued from the CY 2022 PFS final rule policies that reflect updated data and revised methods.

TABLE 134: Reasons for Proposed Change in Burden Compared to the Currently Approved CY 2023 Information Collection Burden

ICR Title	Proposed Changes in burden due to CY 2023 proposed rule policies	Proposed Adjustments in burden continued from CY 2022 PFS final rule policies due to revised methods or updated data
QCDR self-nomination and other Requirements (see section V.B.9.c.(2)(a), Table 97)	None	Increase in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Qualified Registry self-nomination and other Requirements (see section V.B.9.c.(3), Table 99)	None	Increase in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
§ 414.1400 Third Party Intermediary Plan Audits (see section V.B.9.c.(4), Table 102)	None	New ICR. Increase in number of respondents and hours due to restructuring the burden for third party intermediaries to submit a targeted audit, CAP, transition plan, or a participation plan.
Open Authorization (OAuth) Credentialing and Token Request Process (see section V.B.9.d., Table 104)	None	Increase in the number of hours due to changes in administrative workflow for the application process.
Quality Payment Program Identity Management Application Process (see section V.B.9.e.(3), Table 109)	None	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section V.B.9.e.(4), Table 111)	Decrease in number of respondents due to the proposed increase in the number of respondents submitting for the MVP quality performance category via the claims collection type.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.9.e.(5), Table 113)	Decrease in number of respondents due to the proposed increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.9.e.(6), Table 115)	Decrease in number of respondents due to the proposed increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
MVP Registration (see section V.B.9.e.(7)(a)(i), Table 117)	Increase in number of respondents due to proposed addition of 5 new MVPs.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
MVP Quality Submission (see section V.B.9.e.(7)(a)(iii), Table 119)	Increase in number of respondents due to proposed addition of 5 new MVPs.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§ 414.1375 (Promoting	None	Decrease in number of respondents due to

ICR Title	Proposed Changes in burden due to CY 2023 proposed rule policies	Proposed Adjustments in burden continued from CY 2022 PFS final rule policies due to revised methods or updated data
Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.9.g.(2), Table 121)		updated projections for the CY 2023 performance period/2025 MIPS payment year.
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.9.g.(3), Table 124)	Increase in the number of hours due to the proposed requirement for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective.	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.9.i., Table 127)	None	Increase in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year
Nomination of MVPs (see section V.B.9.k., Table 129)	None	Decrease in number of respondents due to updated projections for the CY 2023 performance period/2025 MIPS payment year.
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.9.m. Table 131)	None	Increase in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year.

C. Summary of Annual Burden Estimates for Changes

TABLE 135: Annual Requirements and Burden Estimates

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	0938-1314	180,365	+60,475	Varies	+79,215	Varies	+8,411,851
TOTAL			varies		varies		

D. Submission of Comments

We have submitted a copy of this rule to OMB for review of the rule's information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the

collections previously discussed, please visit CMS's website at *PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1770–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing to make payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 (CAA, 2021); sections 301, 302, 303, 304, and 305 under the Consolidated Appropriations Act, 2022 (CAA, 2022); and sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018, section 90004 of the Infrastructure Investment and Jobs Act, and section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act. . Our proposed policies in this rule specifically address: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; improvements to the Medicare Shared Savings Program (Shared Savings Program) requirements that promote health equity and strengthen financial incentives for participation; updates to the Quality Payment Program; updates to the Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); and updates to the Medicare Ground Ambulance Data Collection System. The proposed policies reflect CMS's stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Extension of Certain Medicare Telehealth Flexibilities, Under Section 1834(m) of the Act, as Amended by the Consolidated Appropriations Act, 2022

Section II.D.1.e. of this proposed rule implements sections 301, 302, 304, and 305, of the Consolidated Appropriations Act, 2022, which extended the geographic restrictions (section 301), extended the temporary expansion of practitioner types who are eligible to furnish Medicare telehealth (section 302), delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS (section 304), and extended audio-only flexibilities for certain telehealth services that would otherwise not be available via telehealth (section 305) after the expiration of the PHE to remain on the Medicare Telehealth Services List for a 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. This proposal is necessary to fulfill the statutory requirement to implement this extension until the 152nd day after the end of the PHE for COVID–19.

b. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs Payable Under Medicare Part B To Provide Refunds With Respect to Discarded Amounts

Section III.A. of this proposed rule implements section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) which requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. These proposals are necessary to fulfill the statutory requirement to implement this policy effective January 1, 2023 and reduce unnecessary Medicare spending for discarded drug.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section III.C.3. of this proposed rule implements sections 303 and 304 of the Consolidated Appropriations Act, 2022. Section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to temporarily continue payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE using the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which, in accordance with section 1834(m)(8)(B) of the Act, is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

Section 304 of the CAA, 2022 delays the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology for a 151-day period beginning on the first day after the end of the public health emergency (PHE) for COVID–19. These proposals are necessary to fulfill these statutory requirements.

We also note in section III.C.3. of this proposed rule we discuss implementation of sections 301 and 305 of the CAA, 2022 that would apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. That is, section 301 of the CAA, 2022 extended the geographic restrictions and section 305 of the CAA, 2022 extended audio-only flexibilities for certain telehealth services that would otherwise not be available via telehealth.

d. Clinical Laboratory Fee Schedule—Revisions Consistent With Recent Statutory Changes

Section III.B.5. of this rule proposes to make conforming regulations text changes for CLFS data reporting requirements due to the enactment of Protecting Medicare and American Farmers from Sequester Cuts Act (S. 610).

By statute, certain clinical laboratories are periodically required to submit private payor rates for certain kinds of lab tests. For Clinical Diagnostic Laboratory Tests (CDLTs) that are not Advanced Diagnostic Laboratory Tests (ADLTs), the Protecting Medicare and American Farmers from Sequester Cuts Act (S. 610) delayed the next data reporting period by one year. Instead of taking place from January 1, 2022 through March 31, 2022, data reporting will now take place from January 1, 2023 through March 31, 2023, based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle (2026, 2029, etc.). Additionally, the statutory phase-in reduction provisions indicate for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

e. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In this rule, we are proposing changes to the electronic prescribing for controlled substances (EPCS) requirement specified in section 2003 of the SUPPORT Act. Previously finalized policies did not include actions for non-compliance after the 2023 year. Additionally, previously finalized policies for statutory exclusions may not have properly identified prescribers that are small prescribers during the compliance period and may have misidentified prescribers in locations with a recognized emergency. The proposals define action for non-compliance for electronic prescribing of controlled substances for the 2024 year and refine policies to better identify prescribers who qualify for the small practice and recognized emergency exceptions to the EPCS requirement.

f. Medicare Ground Ambulance Data Collection System

Section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. In this proposed rule, we are proposing a series of changes to the Medicare Ground Ambulance Data Collection System including the proposal to update § 414.626(d)(1) and (e)(2) to give us the necessary flexibility to specify how ground ambulance organizations should submit the hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational, and proposed revisions to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

g. Quality Payment Program

This proposed rule is also necessary to make changes to the Quality Payment Program to move the Quality Payment Program forward to focus more on measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and encourage participation in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for MIPS is not required to be coordinated across performance categories. These policies are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories, and make changes to scoring that will provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. RHCs and FQHCs

In section III.C.2. of this proposed rule, we are proposing to include chronic pain management (CPM) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code GYYY1 would be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, we propose no change to the average used to calculate the G0511 payment rate.

In addition, in section III.C.2. of this proposed rule we discuss the new coding and payment for general behavioral health integration (BHI) services (HCPCS code GBHI1). We explain that since clinical psychologists (CPs) and clinical social workers (CSWs) are considered practitioners that can provide services in RHCs/FQHCs, we acknowledge when CPs and CSWs provide the services described in HCPCS code GBHI1 in an RHC or FQHC, they can bill HCPCS code G0511.

These proposals are necessary in that we evaluate coding proposals in this rule and their applicability to RHCs and FQHCs.

Section III.C.4. of this proposed rule proposes to provide discussion and clarification regarding the use of short-period cost reports vs 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs. This proposal is necessary to accurately reflect the costs of providing RHC services and will establish a more accurate base from which the payment limits will be upgraded going forward.

b. Clinical Laboratory Fee Schedule (CLFS) Specimen Collection and Travel Allowance

Section III.B.6. of this rule proposes to clarify and codify the CLFS specimen collection and travel allowance payment policies.

In general, section 1833(h)(3) of the Act requires the Secretary to pay a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). CMS' long-standing instructions regarding the statutory requirements for CLFS specimen collection and travel allowance are described in Medicare Claims Processing manual guidance. OIG and other interested parties have expressed concerns regarding inconsistent MAC implementation of the payment policies as well as unclear or conflicting guidance to providers related to the CLFS travel allowance. In the CY 2022 PFS final rule we solicited comments regarding these two payment policies; commenters supported clarification to the existing policy and also made suggestions regarding possible refinements.

Describing and codifying the payment policies related to CLFS specimen collection and travel allowance are necessary to clarify existing policy, address concerns expressed by interested parties, and reduce administrative burden.

c. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In section III.F. of this proposed rule, we explain that because of the inconsistencies in the voluntarily reported ASP data for orally-administered methadone, which reflects data from a small subset of methadone manufacturers, we do not believe this voluntarily reported ASP data for orally administered methadone currently provides a reliable source for pricing the methadone codes. We previously issued an interim final rule with comment period to establish a limited exception to the methodology for determining the payment amount for the drug component of an episode of care under the OTP benefit in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021. For CY 2023 and subsequent years, we are proposing to revise our methodology for pricing methadone under the OTP benefit, specifically, the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone, so that it would not rely on voluntarily-submitted ASP data. We believe this proposal

would stabilize the payment amount for methadone dispensed by OTPs during an episode of care and therefore maintain access to treatment with methadone in the OTP setting for Medicare beneficiaries. Additionally, in section III.F. of this proposed rule, we are proposing to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk code describing a longer duration of psychotherapy compared to the current crosswalk code. We believe this proposal is needed in order to more accurately reflect the resource costs involved with furnishing therapy in the OTP setting.

d. Medicare Part B Payment for Preventive Vaccine Administration Services

Sections III.H.2. and 3. of this proposed rule discuss proposals that implement policies impacting the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit. Section III.H.4. of this proposed rule proposes to clarify the timing of payment policies for COVID–19 vaccines and COVID–19 monoclonal antibody products. These proposals are necessary to provide stable payment for preventive vaccine administration to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

e. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

We propose to modify nonemergency, repetitive, scheduled ambulance policy at § 410.40(e)(2)(ii) by clarifying that (1) the physician certification statement and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance; and (2) that coverage includes observation or other services rendered by qualified ambulance personnel. Existing regulations at § 410.40(e)(2) are interpreted too narrowly by some interested parties, excluding beneficiaries in need of monitoring. This proposed language clarifies the intent of existing regulatory language by explicitly stating that beneficiaries who may not be in need of tangible services, but otherwise are in need of monitoring, qualify for this limited ambulance benefit. This is not a statutorily-mandated provision but addresses a longstanding ambiguity potentially affecting vulnerable populations.

f. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

In CY 2019, the last year for which incidence data are available, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[536] The Center for Disease Control and Prevention (CDC) advises, ''Colorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [537] This proposed rule would expand coverage for colorectal cancer screening tests by reducing the minimum age payment limitation for certain tests from 50 to 45 years of age. In addition, we propose to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Our proposals would update Medicare coverage and payment policies to align with our new understanding of CRC screening, the latest recommendations from the U.S. Preventive Services Task Force and recommendations from professional societies and other appropriate organizations. We propose to expand coverage of colorectal cancer screening tests by exercising our authority under sections 1834(n) and 1861(pp)(1)(D) of the Act. We believe these proposals would expand access to quality care and improve health outcomes through prevention, early detection, more effective treatment and reduced mortality. Moreover, it would directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC.

g. Removal of Selected National Coverage Determinations

CMS periodically identifies and proposes to remove National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries. Since the CY 2021 PFS final rule (85 FR 84472), we have used notice and comment rulemaking to obtain public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically, nationally covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). As described in section III.G. of this proposed rule, we are proposing to remove NCD 160.22 Ambulatory EEG Monitoring (06/12/1984), because the NCD contains outdated language that is inconsistent with, and contrary to current standards of care. We believe that allowing local contractor discretion to make coverage decision for this service better serves the needs of the Medicare program and its beneficiaries. We estimate there would be de minimis change to 2023 payments, compared to 2021 because this is a long-established service for which the MACs already have LCDs and guidance articles. Therefore, we believe removing the outdated NCD would allow MACs to update local coverage guidance for this established diagnostic test, but would not result in significant changes to utilization or payments.

h. Medicare Shared Savings Program

As we seek to advance the overall value-based care strategy of growth, alignment, and equity, we are proposing modifications to the Medicare Shared Savings Program to increase program participation by supporting organizations new to value-based care and shared savings, especially for organizations serving underserved populations, and providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign their care processes to be successful under risk arrangements. As part of this effort, we are proposing advance investment payments to new, low-revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives. To address the social needs of people with Medicare, these payments would increase when more people who are dually eligible and/or who live in areas with high deprivation (measured by the area deprivation index (ADI)) are attributed to the ACO. We are also building on the existing Shared Savings Program benchmarking

[536] *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[537] *https://www.cdc.gov/cancer/colorectal/basic_info/screening/.*

methodology by proposing modifications to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance on their benchmarks, to address the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks, and to strengthen the business case for participation for ACOs serving high-risk and high dually eligible populations, which would help sustain participation and grow the program. Additionally, we are proposing modifications to the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment. We are also proposing changes to the quality reporting and the quality performance requirements to support the transition of ACOs to all payer quality measure reporting. These proposals include implementing a health equity adjustment to an ACO's MIPS quality performance category score to recognize high performing ACOs serving a high proportion of underserved beneficiaries. Finally, we are proposing changes that are important for improved operations of the Shared Savings Program, including policies to reduce ACO administrative burden while maintaining program integrity.

i. Provider Enrollment and DMEPOS Conditions of Payment

This proposed rule is also needed to make regulatory enhancements to our provider enrollment policies and to our DMEPOS conditions of payments. These provisions focus on, but are not limited to: (1) expanding the bases for denying or revoking a provider's or supplier's Medicare enrollment; (2) subjecting a greater number of providers and suppliers, such as skilled nursing facilities, to the highest level of screening, which includes fingerprinting all 5 percent or greater owners of these providers and suppliers; and (3) denying payment to DMEPOS suppliers that are not appropriately licensed. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and that owners of these entities are carefully screened. As explained in section III.J. of this proposed rule, we believe that fulfilling both of these objectives would assist in protecting the Trust Funds and Medicare beneficiaries.

j. Proposal To Revise HCPCS Level II Coding Procedures for Wound Care Management Products

The HCPCS is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The HCPCS Level I code set is comprised of Current Procedural Terminology (CPT®) codes, which are owned and maintained by the American Medical Association. The HCPCS Level II code set is used primarily to identify items, services, supplies, and equipment that are not identified by CPT® codes. CMS updates and maintains the HCPCS Level II code set on a periodic and routine basis.

One of the categories of items and supplies that are typically described by HCPCS Level II codes are wound care management products, which are regulated by the Food and Drug Administration. In order to provide a more uniform and permanent approach to coding for wound care management products, we are making five proposals in this proposed rule: (1) that the assignment of A codes to all wound care management products (that are not regulated by FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products to which we previously assigned a Q code; (2) to discontinue all existing Q codes for wound care management products; (3) to, prior to the assignment of an A code, require products with an existing Q code that were described by the applicant as a 361 HCT/P to submit a HCPCS Level II re-application within 12 months of the effective date of the final rule (that is, January 1, 2024); (4) to require a recommendation letter from the FDA's TRG to be submitted as part of the HCPCS Level II application for all wound care management products described by the applicant as a 361 HCT/P, regardless if it is a first time application or re-application for a product with an existing Q code; and (5) to evaluate HCPCS Level II coding applications for all 361 HCT/P wound care management products through our biannual coding cycles for non-drugs and non-biological products, rather than on a quarterly basis, beginning January 1, 2024. These proposals align with our proposal in section II.J. of this proposed rule that all wound care management products (that are not regulated by FDA as drugs or biological products that would otherwise be eligible for separate payment under section 1847A of the Act) would be covered under section 1861(s)(2)(A) of the Act as incident to supplies that are commonly furnished in the physician office setting.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a

substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement provisions of the statute. We provide information for each of the proposed policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2022 with payment rates for CY 2023 using CY 2021 Medicare utilization. The payment impacts described in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2023, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, the Protecting Medicare and American Farmers from Sequester Cuts Act provided a 3.00 percent increase in PFS payment amounts for services furnished on or after January 1, 2022, and before January 1, 2023 and required that the increase shall not be taken into account in determining PFS payment rates for subsequent years. The expiration of this 3.00 percent increase in payment amounts will result in the CY 2023 conversion factor being calculated as though the 3.00 percent increase for the CY 2022 conversion factor had never been applied.

To calculate the CY 2023 PFS conversion factor (CF), we took the CY 2022 conversion factor without the 1-year 3.00 percent increase provided by the CAA and multiplied it by the BN adjustment required as described in the preceding paragraphs. We estimate the CY 2023 PFS CF to be 33.0775 which reflects the BN adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.00 percent increase for services furnished in CY 2022, as provided in the CAA. We estimate the CY 2022 anesthesia CF to be 20.7191 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

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TABLE 136: Calculation of the CY 2023 PFS Conversion Factor

CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.55 percent (0.9845)	
CY 2023 Conversion Factor		**33.0775**

TABLE 137: Calculation of the CY 2023 Anesthesia Conversion Factor

CY 2022 National Average Anesthesia Conversion Factor		21.5623
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		20.9343
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.55 percent (0.9845)	
CY 2023 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.53 percent (1.0053)	
CY 2023 Conversion Factor		**20.7191**

Table 138 shows the payment impact of the policies contained in this proposed rule on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 138 (CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 138.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2021 utilization and CY 2022 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2023 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2023 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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Part II—Continued

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts; Proposed Rule

TABLE 138: CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$232	0%	-1%	0%	-2%
Anesthesiology	$1,741	-1%	0%	0%	-1%
Audiologist	$70	0%	1%	-1%	0%
Cardiac Surgery	$197	-1%	-1%	0%	-1%
Cardiology	$6,298	0%	-1%	0%	-1%
Chiropractic	$669	-1%	1%	0%	0%
Clinical Psychologist	$784	-1%	0%	-1%	-2%
Clinical Social Worker	$853	-1%	0%	-1%	-2%
Colon and Rectal Surgery	$155	-1%	-1%	0%	-1%
Critical Care	$351	1%	0%	1%	1%
Dermatology	$3,751	-1%	0%	0%	0%
Diagnostic Testing Facility	$811	0%	3%	0%	2%
Emergency Medicine	$2,530	0%	0%	1%	1%
Endocrinology	$532	0%	0%	0%	0%
Family Practice	$5,777	0%	0%	0%	0%
Gastroenterology	$1,589	0%	0%	1%	0%
General Practice	$371	0%	0%	0%	0%
General Surgery	$1,758	-1%	-1%	0%	-1%
Geriatrics	$175	2%	0%	0%	3%
Hand Surgery	$255	-1%	0%	0%	0%
Hematology/Oncology	$1,707	0%	-1%	0%	-1%
Independent Laboratory	$594	0%	-1%	0%	-1%
Infectious Disease	$586	4%	0%	1%	5%
Internal Medicine	$9,804	2%	0%	1%	3%
Interventional Pain Mgmt	$924	-1%	-1%	0%	-1%
Interventional Radiology	$465	-1%	-3%	0%	-4%
Multispecialty Clinic/Other Phys	$150	0%	-1%	0%	0%
Nephrology	$2,021	1%	0%	0%	1%
Neurology	$1,397	0%	0%	0%	-1%
Neurosurgery	$727	-1%	0%	1%	0%
Nuclear Medicine	$53	-1%	-1%	-1%	-3%
Nurse Anes / Anes Asst	$1,116	-1%	0%	0%	-1%
Nurse Practitioner	$5,802	1%	0%	0%	2%
Obstetrics/Gynecology	$592	-1%	0%	0%	-1%
Ophthalmology	$4,835	-1%	0%	0%	0%
Optometry	$1,306	-1%	0%	0%	-1%
Oral/Maxillofacial Surgery	$72	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,461	-1%	0%	0%	0%
Other	$58	0%	-1%	0%	-2%
Otolarngology	$1,134	-1%	0%	0%	-1%
Pathology	$1,163	-1%	0%	0%	-1%
Pediatrics	$57	0%	0%	0%	0%
Physical Medicine	$1,090	2%	0%	0%	2%
Physical/Occupational Therapy	$4,978	-1%	1%	-1%	-1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Physician Assistant	$3,165	0%	0%	0%	0%
Plastic Surgery	$320	-1%	0%	0%	0%
Podiatry	$1,991	-1%	-1%	0%	-2%
Portable X-Ray Supplier	$77	0%	2%	0%	1%
Psychiatry	$978	1%	0%	0%	2%
Pulmonary Disease	$1,395	1%	0%	1%	2%
Radiation Oncology and Radiation Therapy Centers	$1,609	-1%	0%	0%	-1%
Radiology	$4,712	-1%	-1%	-2%	-3%
Rheumatology	$546	-1%	-1%	0%	-2%
Thoracic Surgery	$315	-1%	-1%	0%	-1%
Urology	$1,752	-1%	-1%	0%	-1%
Vascular Surgery	$1,098	0%	-3%	0%	-3%
Total	$90,953	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

We have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately owned physician practices and free standing supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. In response to interested party feedback, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2023 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For this rulemaking cycle, we are providing an additional impact table that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 139.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2021 utilization and CY 2022 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2023 combined impact on total allowed charges.

TABLE 139: CY 2023 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$232	-2%
	Non-Facility	$223	-2%
	Facility	$8	0%
ANESTHESIOLOGY	*TOTAL*	$1,741	-1%
	Non-Facility	$366	-4%
	Facility	$1,375	-1%
AUDIOLOGIST	*TOTAL*	$70	0%
	Non-Facility	$68	0%
	Facility	$2	-1%
CARDIAC SURGERY	*TOTAL*	$197	-1%
	Non-Facility	$38	-3%
	Facility	$159	-1%
CARDIOLOGY	*TOTAL*	$6,298	-1%
	Non-Facility	$4,631	-2%
	Facility	$1,667	1%
CHIROPRACTIC	*TOTAL*	$669	0%
	Non-Facility	$668	0%
	Facility	$1	-1%
CLINICAL PSYCHOLOGIST	*TOTAL*	$784	-2%
	Non-Facility	$608	-2%
	Facility	$176	-2%
CLINICAL SOCIAL WORKER	*TOTAL*	$853	-2%
	Non-Facility	$655	-2%
	Facility	$198	-3%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
COLON AND RECTAL SURGERY	*TOTAL*	$155	-1%
	Non-Facility	$56	-1%
	Facility	$100	-1%
CRITICAL CARE	*TOTAL*	$351	1%
	Non-Facility	$53	-1%
	Facility	$298	2%
DERMATOLOGY	*TOTAL*	$3,751	0%
	Non-Facility	$3,615	0%
	Facility	$136	0%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$811	2%
	Non-Facility	$811	2%
	Facility	$	
EMERGENCY MEDICINE	*TOTAL*	$2,530	1%
	Non-Facility	$231	-1%
	Facility	$2,299	1%
ENDOCRINOLOGY	*TOTAL*	$532	0%
	Non-Facility	$427	-1%
	Facility	$105	3%
FAMILY PRACTICE	*TOTAL*	$5,777	0%
	Non-Facility	$4,630	-1%
	Facility	$1,148	5%
GASTROENTEROLOGY	*TOTAL*	$1,589	0%
	Non-Facility	$603	-1%
	Facility	$986	0%
GENERAL PRACTICE	*TOTAL*	$371	0%
	Non-Facility	$300	-1%
	Facility	$70	4%
GENERAL SURGERY	*TOTAL*	$1,758	-1%
	Non-Facility	$509	-1%
	Facility	$1,249	-1%
GERIATRICS	*TOTAL*	$175	3%
	Non-Facility	$98	0%
	Facility	$78	6%
HAND SURGERY	*TOTAL*	$255	0%
	Non-Facility	$135	-1%
	Facility	$120	0%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,707	-1%
	Non-Facility	$1,130	-2%
	Facility	$577	1%
INDEPENDENT LABORATORY	*TOTAL*	$594	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$594	-1%
	Facility	$	
INFECTIOUS DISEASE	*TOTAL*	$586	5%
	Non-Facility	$93	-2%
	Facility	$493	6%
INTERNAL MEDICINE	*TOTAL*	$9,804	3%
	Non-Facility	$5,047	-1%
	Facility	$4,757	7%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$924	-1%
	Non-Facility	$729	-2%
	Facility	$195	0%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$465	-4%
	Non-Facility	$365	-4%
	Facility	$100	0%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$150	0%
	Non-Facility	$75	-1%
	Facility	$74	1%
NEPHROLOGY	*TOTAL*	$2,021	1%
	Non-Facility	$1,280	-1%
	Facility	$741	6%
NEUROLOGY	*TOTAL*	$1,397	-1%
	Non-Facility	$943	-1%
	Facility	$454	1%
NEUROSURGERY	*TOTAL*	$727	0%
	Non-Facility	$131	-1%
	Facility	$597	0%
NUCLEAR MEDICINE	*TOTAL*	$53	-3%
	Non-Facility	$50	-3%
	Facility	$3	4%
NURSE ANES / ANES ASST	*TOTAL*	$1,116	-1%
	Non-Facility	$25	-5%
	Facility	$1,091	-1%
NURSE PRACTITIONER	*TOTAL*	$5,802	2%
	Non-Facility	$3,778	0%
	Facility	$2,024	5%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$592	-1%
	Non-Facility	$409	-1%
	Facility	$183	0%
OPHTHALMOLOGY	*TOTAL*	$4,835	0%
	Non-Facility	$3,445	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Facility	$1,390	0%
OPTOMETRY	*TOTAL*	$1,306	-1%
	Non-Facility	$1,245	-1%
	Facility	$60	0%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$72	-2%
	Non-Facility	$61	-2%
	Facility	$12	-1%
ORTHOPEDIC SURGERY	*TOTAL*	$3,461	0%
	Non-Facility	$1,561	-1%
	Facility	$1,900	0%
OTHER	*TOTAL*	$58	-2%
	Non-Facility	$47	-2%
	Facility	$11	0%
OTOLARNGOLOGY	*TOTAL*	$1,134	-1%
	Non-Facility	$901	-1%
	Facility	$233	0%
PATHOLOGY	*TOTAL*	$1,163	-1%
	Non-Facility	$1,138	-1%
	Facility	$26	-1%
PEDIATRICS	*TOTAL*	$57	0%
	Non-Facility	$37	-1%
	Facility	$20	3%
PHYSICAL MEDICINE	*TOTAL*	$1,090	2%
	Non-Facility	$576	-2%
	Facility	$514	7%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$4,978	-1%
	Non-Facility	$4,978	-1%
	Facility	$	
PHYSICIAN ASSISTANT	*TOTAL*	$3,165	0%
	Non-Facility	$2,099	-1%
	Facility	$1,066	2%
PLASTIC SURGERY	*TOTAL*	$320	0%
	Non-Facility	$141	-1%
	Facility	$179	0%
PODIATRY	*TOTAL*	$1,991	-2%
	Non-Facility	$1,773	-2%
	Facility	$218	0%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$77	1%
	Non-Facility	$77	1%
PSYCHIATRY	*TOTAL*	$978	2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$525	-1%
	Facility	$453	5%
PULMONARY DISEASE	*TOTAL*	$1,395	2%
	Non-Facility	$584	-1%
	Facility	$811	4%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,609	-1%
	Non-Facility	$1,540	-1%
	Facility	$69	-1%
RADIOLOGY	*TOTAL*	$4,712	-3%
	Non-Facility	$4,486	-3%
	Facility	$226	-1%
RHEUMATOLOGY	*TOTAL*	$546	-2%
	Non-Facility	$489	-2%
	Facility	$56	0%
THORACIC SURGERY	*TOTAL*	$315	-1%
	Non-Facility	$66	-3%
	Facility	$249	-1%
UROLOGY	*TOTAL*	$1,752	-1%
	Non-Facility	$1,255	-1%
	Facility	$496	-1%
VASCULAR SURGERY	*TOTAL*	$1,098	-3%
	Non-Facility	$813	-4%
	Facility	$285	-1%
TOTAL	***TOTAL***	$90,953	0%
	Non-Facility	$61,213	-1%
	Facility	$29,739	2%

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2. CY 2023 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including infectious disease, internal medicine, geriatrics, diagnostic testing facility, and physical medicine reflect increases relative to other physician specialties. These increases can largely be attributed to the revaluation of the other E/M services and/or the second year transition to updated clinical labor pricing. The services that make up these specialties rely primarily on E/M services or on clinical labor for their practice expense costs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including clinical social workers, clinical psychologists, radiology and interventional radiology, vascular surgery, and nuclear medicine, reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of the revaluation of other E/M services and/or the second year transition to updated clinical labor pricing. The services that make up these specialties were also negatively affected by updated malpractice premium data for CY 2023, or rely primarily on supply/equipment items for their practice expense costs and therefore were affected negatively by the transition to updated clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of

AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 138), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 138 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2021 utilization data, Total RVUs change between −1 percent and 1 percent for more than 45 percent of practitioners, representing more than 44 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as chiropractic, hand surgery, ophthalmology, optometry, and orthopedic surgery, exhibit little variation in changes in total RVUs per practitioner. For these specialties, more than 90 percent of these practitioners will experience a change in Total RVUs between −1 percent and 1 percent. The specific service mix *within* a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 138 (CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates a 5 percent increase in RVUs for the infectious disease specialty as a whole, however, only 36 percent of infectious disease specialty practitioners—representing over 51 percent of Total RVUs for the specialty—would experience a 5 percent or more increase in Total RVUs. Meanwhile, nearly 12 percent of infectious disease specialty practitioners would experience 1 percent or more decreases in Total RVUs, and these practitioners account for about 6 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

Many interested parties have requested that CMS maintain the 3.00 percent increase in PFS payment amounts that was specified in the Protecting Medicare and American Farmers from Sequester Cuts Act for services furnished during CY 2022. We remind readers that this increase was provided through a time-limited amendment to the statute, which CMS does not have legal authority to alter. The expiration of this 3.00 percent increase in payment amounts will result in the CY 2023 conversion factor being calculated as though the 3.00 percent increase for the CY 2022 conversion factor had never been applied. Several interested parties have requested clarification regarding whether the specialty impacts displayed in Table 138 reflected the expiration of the 3.00 percent CAA provision for CY 2023. We can clarify for the commenters that the specialty impacts displayed in Table 138 reflect changes that take place within the pool of total RVUs. The specialty impacts table therefore includes any changes in spending which result from finalized policies within BN (such as the revaluation of other E/M codes in CY 2023 or the clinical labor pricing update in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to BN adjustment, and therefore, have a neutral impact across all specialties. The expiration of the 3.00 percent CAA provision for CY 2023 is a statutory change that takes place outside of BN, and therefore, is not captured in the specialty impacts displayed in Table 138.

b. Impact

Column F of Table 138 displays the estimated CY 2023 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2023 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.* We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

D. Changes Related to Telehealth Services

In last year's final rule, we discussed various flexibilities that would expire at the end of the PHE. Further, we clarified certain policies that were initially implemented as temporary policies, and subsequently made permanent by provisions of the CAA, 2021 that amended section 1834(m) of the Act (refer to 86 FR 65055–65063). Also, we note that the CAA, 2022 includes provisions that further amend section 1834(m) of the Act. For a detailed discussion of our implementation of the CAA, 2022 provisions refer to section II.B of this proposed rule.

Following the expiration of the PHE for COVID–19, Medicare telehealth will see changes occur in a number of areas. CMS implemented many temporary policy changes during the PHE to facilitate continued safe access to care during the pandemic, and that those changes will end with the expiration of the PHE ends or, in the case of some policies, after 151 days following the end of the PHE as specified in the relevant sections of the CAA, 2022.

Following the expiration of the flexibilities put in place during the PHE for COVID–19, the statutory and regulatory restrictions on payment for Medicare telehealth services under section 1834(m) of the Act and our regulations at §§ 410.78 and 414.65 will apply once again.

For most Medicare telehealth services, payment will be made only when furnished by certain types of physicians and practitioners to patients located in specified types of medical settings (originating sites) located in mostly rural areas, and only when the service is furnished using audio and video equipment permitting two-way, real-time interactive communication between the patient and furnishing practitioner. There are limited exceptions to these restrictions that allow Medicare telehealth services to be furnished without geographic limitations, to patients in their homes, and in some cases using audio-only technology, when the services are for the diagnosis, evaluation, or treatment of a mental health disorder (including a substance use disorder (SUD), including opioid misuse). There are also limited statutory exceptions for home dialysis monthly ESRD-related visits and for services for purposes of diagnosis, evaluation or treatment of symptoms of an acute stroke, to allow Medicare telehealth services to be furnished without geographic limitations, and to patients in their homes or certain other locations.

As such, after the expiration of the flexibilities put in place during the PHE, we expect a significant reduction in the volume of Medicare telehealth services overall, and a corresponding reduction in aggregate spending for Medicare telehealth services. We further expect that many of the services that have been furnished via telehealth during the PHE will return to in-person settings. However, because the provisions of the CAA, 2021 and CAA, 2022 required permanent changes to remove previous restrictions on the use of telehealth for the diagnosis, evaluation or treatment of a mental health disorder (including a substance use disorder (SUD), including opioid use disorder), we anticipate that volume and spending for Medicare telehealth mental health services will increase from pre-pandemic levels coming years.

In this proposed rule, we propose to continue including on the Medicare Telehealth Services List, either permanently or temporarily through the end of CY 2023, many of the services added to the list during the PHE. However, after the expiration of the flexibilities put in place during the PHE, payment for Medicare telehealth services will be subject to the statutory and regulatory limitations described previously in this section of the RIA. Compared to overall utilization of these services during the PHE, we do not expect new significant overall growth in Medicare telehealth services by aggregate volume. Further, we estimate that the proposed addition of telehealth services added to the Medicare Telehealth Services List will have a negligible impact on PFS expenditures.

We are also proposing to implement provisions of the CAA, 2022 that extend the application of certain Medicare telehealth flexibilities for an additional 151 days after the end of the PHE for COVID–19, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S.; allowing the extended scope of eligible telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists; extending payment for telehealth services furnished by FQHCs and RHCs; and delaying the requirement that there be an in-person visit with the physician or practitioner within 6 months before an initial mental health telehealth service. We anticipate that these proposals will result in continued utilization of Medicare telehealth services during the remainder of the PHE and the immediate subsequent 151 days at levels comparable to observed utilization of these services thus far during the PHE for COVID–19.

Regarding our proposal to retain on the Medicare Telehealth Services List until the end of CY 2023 the services that we added to the list on a temporary Category 3 basis, we believe our proposals would provide clarity to interested parties, but will have a negligible impact on PFS expenditures. For example, outside the circumstances and flexibilities available during the PHE, services that are permanently included on the Medicare Telehealth Services List are furnished via telehealth, on average, less than 0.1 percent of the time they are reported.[538] The statutory and regulatory requirements for payment of Medicare telehealth services that apply outside the circumstances of the PHE have limited increases in utilization.

E. Other Provisions of the Regulation

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs Payable Under Medicare Part B To Provide Refunds With Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the payment limit for the drug, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In section III.A of this proposed rule, we are proposing implementation of this provision including: how discarded amounts of drugs are determined; a definition of which drugs are subject to refunds (and exclusions); when and how often CMS will notify manufacturers of refunds; when and how often payment of refunds from manufacturers to CMS is required; refund calculation methodology; a dispute resolution process; and enforcement provisions.

To estimate anticipated quarterly refund amounts due from manufacturers, we analyzed JW modifier data from 2020 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[539] Overall in the 2020 calendar year, Medicare paid nearly $720 million for discarded amounts of drugs from a single-dose container or single-use package paid under Part B. In that year, there were 39 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 8 would not meet the proposed definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are multiple source drug codes; 5 would be excluded from the proposed definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling. After these exclusions, there were 26 billing and payment codes that would meet the proposed definition of refundable single-dose container or single-use package drug and have 10 percent or more discarded units.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage). Then, we multiplied that percentage by the CY 2020 total allow amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based

[538] *https://www.cms.gov/medicare-telemedicine-snapshot.*

[539] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

on this data, there would be approximately $141 million dollars in refunds due from manufacturers for the calendar year of 2020 ($35.4 million dollars each calendar quarter). See Table 140.

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TABLE 140: Estimated Refund Amounts Based on CY 2020 JW Modifier Data

HCPCS Code	CY 2020 Total Allowed Amount	Percent Units Discarded	Percent Discarded Units – 10%	Estimated Annual Refund	Estimated Quarterly Refund
J9043	$135,486,070.48	28.14%	18.14%	$24,577,173.19	$6,144,293.30
J9041	$400,736,898.62	26.67%	16.67%	$66,802,841.00	$16,700,710.25
J0223	$3,953,268.84	20.80%	10.80%	$426,953.03	$106,738.26
Q4195	$6,233,097.24	20.47%	10.47%	$652,605.28	$163,151.32
J0775	$55,922,761.61	20.18%	10.18%	$5,692,937.13	$1,423,234.28
J9262	$342,668.12	19.96%	9.96%	$34,129.74	$8,532.44
J0565	$2,724,776.12	19.55%	9.55%	$260,216.12	$65,054.03
J2796	$240,489,959.82	16.83%	6.83%	$16,425,464.26	$4,106,366.06
J9309	$49,591,437.88	15.79%	5.79%	$2,871,344.25	$717,836.06
Q4106	$2,098,353.95	15.07%	5.07%	$106,386.55	$26,596.64
J1640	$7,204,322.44	14.87%	4.87%	$350,850.50	$87,712.63
J9153	$8,651,250.34	14.63%	4.63%	$400,552.89	$100,138.22
J9264	$352,102,440.73	14.46%	4.46%	$15,703,768.86	$3,925,942.21
J9179	$45,528,228.20	12.60%	2.60%	$1,183,733.93	$295,933.48
J2562	$17,986,116.53	12.41%	2.41%	$433,465.41	$108,366.35
Q4101	$2,701,473.78	12.11%	2.11%	$57,001.10	$14,250.27
J9229	$25,178,218.24	12.06%	2.06%	$518,671.30	$129,667.82
J3300	$8,454,347.46	11.44%	1.44%	$121,742.60	$30,435.65
J0485	$65,351,086.26	11.43%	1.43%	$934,520.53	$233,630.13
J9042	$167,324,055.19	11.41%	1.41%	$2,359,269.18	$589,817.29
J2997	$71,164,289.22	11.34%	1.34%	$953,601.48	$238,400.37
J9352	$9,562,087.18	10.95%	0.95%	$90,839.83	$22,709.96
J0291	$264,734.03	10.80%	0.80%	$2,117.87	$529.47
J9205	$54,328,144.16	10.50%	0.50%	$271,640.72	$67,910.18
J9307	$22,242,951.07	10.27%	0.27%	$60,055.97	$15,013.99
J9228	$375,059,594.99	10.06%	0.06%	$225,035.76	$56,258.94
			Total	**$141,516,918.47**	**$35,379,229.62**

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There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved, this estimate does not consider newer drugs that would meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months from this definition, we would expect impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code would become a multiple source drug code and would no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers would not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on

the ASP drug pricing file [540] and implementation of section 90004 of the Infrastructure Act would not be restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

a. Impacts Related to the Proposed Dispute Resolution Process

As described in section V.B.1. of this proposed rule, the information collection requirements, we estimate the annual burden per respondent/recordkeeper to be 40 hours. If we anticipate no more than 10 disputes per year, the total annual reporting and/or recordkeeping burden would be 400 hours (10 error reports per year × 40 hours per respondent). We estimate an annual cost of this burden to be $15,800 ($39.50/hour × 400 hours).

2. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.C.2. of this proposed rule, we are proposing to include chronic pain management services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Since HCPCS code GYYY1 would be valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, we propose no change to the average used to calculate the G0511 payment rate.

In addition, in section III.C.2. of this proposed rule we discuss the new coding and payment for general behavioral health integration services (HCPCS code GBHI1). We explain that since clinical psychologists (CPs) and clinical social workers (CSWs) are considered practitioners that can provide services in RHCs/FQHCs, we acknowledge when CPs and CSWs provide the services described in HCPCS code GBHI1 in an RHC or FQHC, they can bill HCPCS code G0511.

In terms of estimated impacts to the Medicare program, expanding use of General Care Management HCPCS code G0511 to include chronic pain management services (GYYY1) and behavioral health integration services (GBHI1) for RHCs and FQHCs would have a negligible impact on Medicare spending because these services are already included.

In section III.C.4. of this proposed rule, we provide a discussion and clarification regarding the use of short-period cost reports vs 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs in accordance with section 1833(f)(3)(A) of the Act. We believe this clarification would have negligible impact on Medicare spending.

3. Clinical Laboratory Fee Schedule

In section III.B. of this proposed rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 4(b) of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, enacted December 10, 2021), we are proposing to make certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are proposing to update certain definitions and revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2023. The PMAFSCA delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2023 through March 31, 2023. Subsequently, the next private payor rate-based CLFS update for these tests would be effective January 1, 2024 instead of January 1, 2023. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the PMAFSCA amendments. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.A. of this proposed rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the PMAFSCA amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to the unforeseen changes in private payor rates due to potential shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting would result in a measurable budgetary impact. In other words, in order to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we would need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, and calculating the updated CLFS rates.

With regard to the proposed conforming changes to our requirements for the phase-in of payment reductions, we note that for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may receive the full 15 percent phase-in reduction in CY2023.

4. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

In section III.D. of this proposed rule, we propose to expand CRC screening test coverage by modifying coverage and payment limitations of certain CRC screening tests to begin at age 45 instead of 50. An updated modeling study that accompanied the May 2021 updated USPSTF CRC screening recommendation found that the most efficient strategy for CRC screening began for individuals at 45 years of age. The expected benefits include longer life and fewer new cases and total deaths from colorectal cancer.[541] We considered the comparatively small population of traditional Medicare enrollees in the affected age group. The CMS website reports that total Medicare beneficiary enrollment in Part A and/or Part B aged 45–54 years in CY 2020

[540] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

[541] *https://www.uspreventiveservicestaskforce.org/uspstf/document/final-modeling-study18/colorectal-cancer-screening.*

totaled only 1,956,634, whereas total Medicare beneficiary enrollment in Part A and/or Part B of all ages totaled 62,840,267.[542]

In addition, we propose to expand CRC screening test coverage to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. We anticipate the impact of beneficiary cost sharing no longer being applicable to the follow-on screening colonoscopy would be balanced, in part or in whole, by the benefits and savings of additional beneficiaries choosing a less expensive and non-invasive stool-based test as their first step in the CRC screening process.

We anticipate that both proposals would result in some additional service utilization, but we also anticipate the additional utilization to be balanced, in part or in whole, by benefits and savings resulting from increased prevention, early detection (allowing for less invasive and more effective treatment) and reduced mortality. We do not anticipate expanding CRC screening test coverage (in accordance with recommendations by the USPSTF and in consultation with other appropriate organizations described earlier in our proposal) to result in a significant impact on the Medicare program.

An internal analysis by the CMS Office of the Actuary of CY 2019 Medicare FFS CRC screening test claims confirmed our understanding that our proposals would not likely result in a significant impact on the Medicare program. Regarding our proposal to expand CRC screening test coverage by modifying coverage and payment limitations of certain CRC screening tests to begin at age 45 instead of 50, we calculated CY 2019 FFS CRC screening test spending and utilization for patients between 45 and 55 years old, estimated CY 2019 Medicare FFS member months by age, and assumed that current colorectal screening test utilization for 45–49 year old patients would increase on a per enrollee basis to that of patients between 50–55. We estimated the impact from additional utilization to be approximately $5 million in additional spending. Regarding our proposal to expand CRC screening test coverage to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result, we matched CY 2019 FFS colonoscopy claims to Cologuard usage claims, identified colonoscopy claims as screening or diagnostic, assumed that all diagnostic colonoscopy claims with a prior Cologuard test had a positive test result, and calculated the applicable beneficiary cost sharing for those claims. We estimated the impact from additional utilization to be approximately $5 million in additional spending.

5. Removal of Selected National Coverage Determinations (NCDs)

We are proposing to remove one older NCD that no longer contains clinically pertinent and current information. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for interested parties and CMS. NCDs generally fall into one of two impact categories. First, eliminating an NCD for items and services that were previously nationally covered means that the item or service will no longer be automatically nationally covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous national coverage determination barred coverage for an item or service under title XVIII, MACs would now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within this policy will be limited, affecting less than one percent of the Medicare FFS population.

By proposing to remove NCD 160.22 Ambulatory EEG Monitoring, we are proposing to go from positive national coverage to local coverage by the MACs. Claims data for 2021 shows that for the 20 CPT/HCPCS codes associated with this NCD, CMS paid 167,242 Medicare FFS claims for approximately 78,267 unique beneficiaries totaling CMS payments of $48,702,876.00. We estimate there will be de minimis change to 2023 payments, compared to 2021 because this is a long-established service for which the MACs already have LCDs and guidance articles. The NCD contains outdated language that is inconsistent with, and contrary to current standards of care. Therefore, we believe removing the outdated NCD will allow MACs to update local coverage guidance for this established diagnostic test, but would not result in significant changes to utilization or payments.

6. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F of this proposed rule, for CY 2023 and subsequent years, we are proposing to revise our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. Under this proposal, we would base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription). We propose to update the methadone payment amount for CY 2023 based on the projected increase in the PPI for Pharmaceuticals for Human Use (Prescription) to reflect the forecasted price growth for prescription drugs for the 2-year period from CY 2021 to 2022 and from CY 2022 to 2023. Because we froze the payment amount for methadone at the 2021 amount for CY 2022, we propose to account for the inflation for both CY 2022 and CY 2023 in setting the payment rate for CY 2023. Based on the 2022 Q1 forecast from IHS Global Inc. (IGI) the proposed CY 2023 methadone payment amount would be $39.29, which is the CY 2022 payment amount of $37.38 increased by a projected 5.1 percent growth in the PPI for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023 ($37.38 * 1.051 = $39.29). IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast various price proxies used in the CMS market baskets. Additionally, we are proposing that if more recent data become subsequently available (for example, a more recent estimate of the PPI), we would use such data in the final rule to determine the final CY 2023 methadone payment amount. For subsequent years, we are proposing to continue to update this rate annually using the PPI for Pharmaceuticals for Human Use (Prescription).

Overall, CMS estimates that the impact of our proposal to revise the OTP methadone pricing methodology would increase Medicare spending by roughly $2.5 million in CY 2023. This estimate is based on actual utilization of the OTP benefit by Medicare beneficiaries under Part B through CY 2021. The estimate does not reflect any additional utilization that may occur in CY 2023.

[542] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-total-enrollment.*

Additionally, as discussed in section III.F of this proposed rule, we are proposing to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), instead of a crosswalk to CPT code 90832 (*Psychotherapy, 30 minutes with patient*), as is our current policy. We believe CPT code 90834 most closely corresponds to a 50-minute therapy session, which interested parties have indicated is the typical amount of therapy received by patients in the first few months of treatment at an OTP. In the CY 2020 PFS final rule (84 FR 62658), we stated that we based the rate for individual therapy in the bundled payment on the 2019 non-facility payment rate for CPT code 90832, which was $68.47. Therefore, to change the rate for individual therapy, we are proposing to substitute the 2019 rate for CPT code 90832 included in the non-drug component of each of the bundled payments for an episode of care with the 2019 PFS non-facility payment rate for CPT code 90834, which was $91.18, to determine an adjusted payment rate for CY 2020 for the non-drug component of each applicable HCPCS code. As described in § 410.67(d)(4)(iii), we would then apply the Medicare Economic Index (MEI) updates for 2021, 2022, and 2023 to these adjusted payment rates to determine the CY 2023 payment amounts for the non-drug component of the bundled payments for an episode of care.

CMS anticipates that the proposed increase to the bundled rates to reflect longer individual therapy sessions would result in an increase of $25.93 to the non-drug component of the weekly bundled payments for HCPCS codes G2067 through G2075 from CY 2022 to 2023. Based on utilization data from Medicare beneficiaries under the OTP benefit through CY 2021, the estimated impact of this policy is an increase in Medicare spending of approximately $27 million in CY 2023. This estimate does not reflect any additional utilization that may occur during CY 2023.

Additionally, as discussed in section III.F. of this proposed rule, we are proposing to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We are also proposing to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary.

We believe the Part B cost impact of the proposed flexibilities for the use of telecommunications policies will be minimal because, we do not expect that this provision will increase the frequency at which medically necessary intake assessments are furnished.

7. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2022, over 11 million people with Medicare receive care from at least one health care provider in one of the 483 ACOs participating in the Medicare Shared Savings Program (Shared Savings Program), the largest value-based payment program in the country. The Shared Savings Program proposed policies advance Medicare's overall value-based care strategy of growth, alignment, and equity, with many proposals overlapping these categories. The proposed policies are designed to reverse recent trends where participation has plateaued in the Shared Savings Program has plateaued, higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to ACOs appears inequitable as evidenced by data indicating underserved populations are less likely to be assigned to a Shared Savings Program and to encourage growth of ACOs in underserved communities based, in part, on recent observations where the highest earning ACOs had a higher proportion of beneficiaries who were members of racial and ethnic minority communities and included a greater proportion of ESRD, disabled, and aged/dual eligible beneficiaries than the lowest earning ACOs.

Stagnation in overall participation in the Shared Savings Program in recent years has coincided with increasing total shared savings outlays, driven by sharply higher shared savings payments to ACOs that were already low spending relative to their region electing to transition to risk in the ENHANCED track. While this type of selection was anticipated in estimating the impacts of the December 2018 final rule (83 FR 67816), it was also assumed that: (1) ACOs making the transition to risk would respond with stronger efforts to improve efficiency, and (2) a broader spectrum of relatively higher-spending ACOs would be influenced by the revised benchmarking methodology to drive down spending for their assigned beneficiaries while participating under the BASIC track glide path in order to ultimately achieve sustainable participation under risk in following agreement periods.

The overall increase in shared savings payments to ACOs transitioning to the ENHANCED track appears to be driven largely by favorable regional benchmark adjustments and the ENHANCED track's higher sharing rate, calling into question whether ACOs selecting risk will further improve efficiency or simply be content to collect steady shared savings by maintaining their spending level relative to their region. Meanwhile, ACO Investment Model participants—a subset of Track 1 ACOs that meaningfully outperformed peer ACOs in reducing spending and earning shared savings over the period from 2016 through 2018—have also dropped out at an elevated frequency before even attempting the risk-free portion of the BASIC track glide path. The spending reductions achieved by AIM ACOs were found to be similar regardless of an AIM ACO's decision to continue or exit the program. Superior financial performance during an initial agreement period under a one-sided mode therefore failed to provide sufficient incentive to overcome a pronounced aversion to risk demonstrated by this otherwise-effective subset of ACOs.[543]

Without modification, the Shared Savings Program is at high risk of increasing overall Medicare spending over the coming decade. ACOs serving patients with low spending will likely continue to dominate the roster of ACOs making the transition to risk. Shared savings payments to low-spending ACOs will increase alongside a growing disincentive for ACOs to serve higher spending populations for whom potential savings from care management would likely be greater.[544] This selective participation is in response to regional benchmark adjustments that have increased shared savings payments to low spending ACOs and has resulted in higher cost beneficiaries, who have the most need for ACO care management, being increasingly excluded from assignment to ACOs participating in the program. It currently appears very unlikely that selective transition to downside risk under the

[543] Trombley, MJ, et al. ACO Investment Model Produced Savings, But the Majority of Participants Exited when Faced with Downside Risk. *Health Affairs.* 2020; 138–146. doi:10.1377/hlthaff.2020.01819.

[544] McWilliams, JM, et al. Early Performance of Accountable Care Organizations in Medicare. *New England Journal of Medicine.* June 2016. 374:2357–2366. DOI: 10.1056/NEJMsa1600142.

current participation options and financial methodology will drive down spending enough to offset increased shared savings payments to ACOs with favorable regional benchmarks. Furthermore, a growing subset of ACOs that elect prospective beneficiary assignment are finding their regional benchmarks to be artificially inflated because of a systematic bias in calculations based on regional FFS expenditures resulting from comparing expenditures for the ACO's own assigned beneficiary population identified based on the offset assignment window, and expenditures for the assignable population of beneficiaries in the ACO's region identified based on the calendar year assignment window. Therefore, the program's baseline trajectory is now projected to increase net Medicare spending by approximately $4.2 billion over the period from 2024–2034, which spans two 5-year agreement periods for ACOs renewing or entering in 2024 and 2025. Absent proposed changes, the program is projected to violate the statutory requirement that provisions implemented under authority of section 1899(i)(3) of the Act not increase spending.

The proposals are designed to increase program participation for new ACOs through advance investment payments to promote health equity and provide ACOs greater choice in the pace of progression to performance-based risk; sustain program participation by reducing the effect of ACO performance on benchmark updates and benchmark rebasing; mitigate the bias in regional expenditure calculations that benefits ACOs electing prospective assignment; strengthen incentives for ACOs serving high risk and high dual populations; improve the risk adjustment methodology to better account for medically complex, high cost beneficiaries while continuing to guard against coding initiatives; increase opportunities for low revenue ACOs in the BASIC track to share in savings by allowing ACOs that do not meet the minimum savings rate (MSR) requirement to share in savings at a lower rate; encourage ACOs to transition more quickly to all-payer quality measure reporting; update the ACO beneficiary assignment methodology; and reduce administrative burden on ACOs.

Reducing the cap on negative regional adjustments to high spending ACOs' benchmarks and offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period are expected to significantly re-engage participation for ACOs serving higher cost beneficiaries. While we are uncertain how large the group of new and re-entering ACOs would be and whether they would have a similar savings potential as the first implementation of Track 1, other proposed incentives targeted to low revenue (typically physician-led) ACOs, like advance investment payments and paying partial shared savings to low-revenue ACOs with savings under their MSR, as well as adjusting rebased benchmarks for prior savings should improve the incentive for new ACOs to join the program and reduce spending to a greater extent than the incentive provided under Track 1. Table 141 shows the combined benchmark and the relative impact that 2024/2025 renewing and new ACOs are expected to have on average over the two 5-year agreement periods from 2024–2034. The Baseline columns show these projections under current program rules and the Proposed columns show the projections for performance under the proposed rule.

TABLE 141: Projected Impacts on Benchmark and Spending for 2024/2025 Renewing, Re-entering and New ACOs

	Renewing ACOs		New ACOs / Re-entering ACOs	
	Baseline	Proposed	Baseline	Proposed
Average Annual Benchmark ($ Billion)	$73	$91	$11	$44
Gross Savings (Impact on Claims, % of Bmark)	-2.7%	-2.8%	-1.3%	-2.7%
AAPM QP Physician Pay Increase (% of Bmark)	0.3%	0.3%	0.3%	0.1%
Shared Savings/(Losses) (% of Bmark)	2.8%	2.1%	2.2%	1.0%
Net Advance Investment (% of Bmark)				0.01%
Net Federal Impact (% of Bmark)	0.4%	-0.4%	1.2%	-1.6%
Net Federal Impact ($Billions)	$2.9	-$3.6	$1.3	-$6.8
10th percentile	-$1.4	-$10	$0.5	-$11
90th percentile	$7.0	$3.0	$2.0	-$3.2

b. Impacts for Renewing ACOs

Renewing ACOs for the projected two 5-year agreement periods are anticipated at baseline to generate higher net shared savings earnings (2.8 percent of benchmark) than actual reductions in spending on claims (2.7 percent of benchmark). After also accounting for higher physician fee schedule payments to qualifying practitioners (QPs), totaling on average 0.3 percent of benchmark over 10 years, this cohort of ACOs is projected to increase net program spending by 0.4 percent of benchmark on average, or $2.9 billion over 10 years. For existing ACOs, the proposed changes would help retain more of the otherwise shrinking subset of ACOs that serve higher spending populations, would remove the bias favoring benchmarks for ACOs electing prospective assignment, and would marginally improve the incentive for efficiency via the use of a three-way blend of the Accountable Care Prospective Trend (ACPT)/national-regional growth rates to update benchmarks and the prior savings adjustment. As a result, overall savings on claims are projected to increase by a small margin to 2.8 percent of benchmark while average shared savings payments would be reduced to an average of 2.1 percent of benchmark. The total 10-year impact for this cohort would flip from a $2.9 billion cost at baseline (range of $1.4 billion savings to $7.0 billion cost at 10th and 90th percentiles) to a $3.6 billion savings under the proposed changes (range of $10 billion savings to $3 billion cost at the 10th and 90th percentiles).

c. Impacts for New ACOs and Re-Entering ACOs

At baseline without the proposed changes, the cohort of new ACOs and re-entering ACOs starting in 2024 would be relatively small (only $11 billion in annual benchmark) and skewed toward ACOs serving beneficiary populations that are already low cost at baseline. Shared savings payments to this group would also be elevated by the bias inflating benchmarks for ACOs electing prospective assignment. At baseline this cohort would increase net program spending by an estimated 1.2 percent of benchmark or $1.3 billion over 10 years (ranging from an increase of $0.5 to $2.0 billion at the 10th and 90th percentiles). Alternatively, under the proposed changes, the cohort of new and re-entering participation starting in 2024 is estimated to increase to $44 billion in combined benchmark per year. An anticipated influx of low revenue physician-led ACOs serving higher cost patients is expected to allow this cohort to produce significantly greater savings on claims (2.7 percent of benchmark) than would be paid out in shared savings (1.0 percent of benchmark) because these ACOs would be starting with lower relative benchmarks than existing low-spending ACOs and they would predominantly be paid under the lower 40 percent sharing rate offered in the BASIC track's one-sided models. After accounting for slightly higher physician fee schedule payments to QPs and a nominal net cost of advance investment payments, this cohort is projected to reduce net program spending about 1.6 percent of benchmark or $6.8 billion over a 10-year period (net savings range from $3.2 billion to $11 billion at the 90th and 10th percentiles).

Average gross savings for this cohort (2.7 percent of benchmark) are projected to roughly match average gross savings for renewing ACOs (2.8 percent of benchmark) despite being less-experienced and heavily concentrated in the BASIC track because they are both serving higher-spending patients presenting greater savings opportunities and because they are anticipated to predominantly include low-revenue ACOs for whom sharing-only incentives are relatively strong despite not being pushed toward risk in their first agreement period. As a percentage of benchmark, these projected gross savings rates are consistent with the savings range estimated for historical performance for the Shared Savings Program detailed in Regulatory Impact Analysis for the December 2018 final rule (83 FR 68047 through 68050) and would represent modest progression from the 1.3 to 2 percent savings estimated by MEDPAC using an ''intent to treat'' approach for evaluating performance through 2016, which was dominated by participation in Track 1.[545]

d. Annual Combined Impacts 2023–2034

As described in Table 142, relative to baseline projections, the combined cohort entering or renewing for agreement periods beginning in 2024 and 2025 is projected to add roughly $50 billion in annual benchmark, reduce claims costs by $15.5 billion, and on net increase aggregate shared savings payments by about $650 million. The proposed rule changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare. Approximately 80 percent of advance investment payments are anticipated to be recovered from shared savings payments by the middle of the second agreement period; the estimate shows $40 million in outstanding advance investment payments by the end of the projection period after an initial $210 million in initial funding. Approximately $60 million in net savings for 2023 is projected for retaining existing higher-spending ACOs that would have otherwise dropped out if not offered the ability to remain in one-sided risk for the remainder of their current agreement period.

More importantly, the Shared Savings Program would increase participation from ACOs serving higher-spending beneficiaries by reducing the negative regional adjustment cap and creating a sharing-only option covering an entire agreement period plus the first 2 years of the succeeding agreement period for eligible ACOs. Advance investment payments and partial shared savings payments for certain ACOs in the BASIC track with savings below their MSR would only marginally increase payments to ACOs while increasing overall program savings by drawing new participation from low revenue ACOs (typically physician-led ACOs), the type that performed well under Track 1. Including a prior savings adjustment as part of benchmark rebasing would broaden the incentive for ACOs to drive down spending over multiple agreement periods by mitigating the ratchet effect for high-spending ACOs, for ACOs in competitive markets with collectively low trend, and for ACOs under prospective assignment that may be concerned about the proposal to remove the favorable bias in regional benchmark calculations. Modifications to the quality scoring system through adding a sliding scale approach to determining shared savings and offering bonus points to higher performing ACOs with a high proportion of underserved populations may increase shared savings payments marginally overall depending on how ACOs may otherwise have progressed in future years against what is still a relatively new quality rubric. The proposed changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare. The impact estimate ranges from a reduction of $8.2 billion to a reduction of $21.4 billion at the 10th and 90th percentiles.

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[545] Report to Congress: Medicare and the Health Delivery System (Chapter 6). MEDPAC publication dated June 2019. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch6_medpac_reporttocongress_sec.pdf.*

TABLE 142: Proposed Rule Projected Impact Relative to Current SSP Baseline (Financial Impacts in $Millions)

Program Year	ACO Participation	ACO Benchmark	Claims	Net ACO Sharing	Advance Investment Cash Flow*	Comb. Fed Impact
2023	34	10,940	-80	20	N/A	-60
2024	128	40,040	-490	70	210-70	-420
2025	140	43,490	-760	-200	-40	-960
2026	137	44,110	-950	-120	-20	-1,070
2027	138	45,800	-1,170	-70	-10	-1,240
2028	143	49,060	-1,370	-40	-10	-1,410
2029	155	54,930	-1,700	-10	-10	-1,710
2030	146	53,700	-1,990	310	-10	-1,680
2031	144	55,210	-2,110	310	0	-1,800
2032	144	57,130	-2,100	220	0	-1,880
2033	138	56,820	-2,120	250	0	-1,870
2034			-670	-90	0	-760
12Y Total			**-15,510**	**650**	**40**	**-14,810**
Low (10th Ptile)				-3,710		-21,410
High (90th Ptile)				820		-8,200
*Total advance investment payments in 2024 shown with first year repayment amount in same row for 2024						

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e. Discussion of Key Proposals and Related Assumptions

The stochastic model and associated assumptions previously described in the December 2018 final rule (83 FR 67816) were updated to produce this estimate. The model continues to assume that high-revenue ACOs are on average only 50 percent as effective as low-revenue ACOs at reducing spending because high-revenue ACOs include a more comprehensive mix of hospitals and other providers and suppliers for whom the incentive to potentially share in a fraction of savings from preventing utilization is weak compared to the immediate revenue from utilization—an expectation that has been supported by evaluation of actual program performance.[546] Updates included accounting for the current mix of participating ACOs in constructing the potential ACOs making up the renewing cohort and considering the population of exiting ACOs to build a sample of higher spending populations that may be added to the program under the proposals that are expected to boost interest in the program from potential ACOs associated with average and higher spending populations. New low-revenue ACOs were assumed to always prefer the extended glidepath unless they expected a regional benchmark at least 3 percent higher than baseline spending, in which case a one-third probability was assigned for the entrant to opt for higher potential earnings under Level E of the BASIC track. The model was also updated to first decrease the baseline savings potential for existing and new ACOs under the current program rules by about 25 to 50 percent (to better match emerging actual performance from selective low-spending ACO participation) which was then scaled up for estimating the proposed impacts to account for new incentives driven mainly by the ACPT and prior savings adjustment, taking the form of a 0 to 50 percent increase in gross savings for low and average spending ACOs and a zero to 100 percent increase for new ACOs serving markedly high spending populations at baseline (at least 10 percent higher than their regional average benchmark spending level). The resulting savings ranges produced by the modeled participation are supported by the proximity to previous estimates of program savings under more balanced participation in Track 1, as noted previously in this section. Savings are expected to increase because of the many new features that would improve the incentive for ACOs to drive down spending over multiple agreement periods. Below is a further discussion of these factors.

Introducing a prospective 5-year growth rate to be blended with the existing retrospective benchmark trend would help address the so-called 'rural glitch' complaint from ACOs and other interested parties and should at least marginally improve the incentive for ACOs to reduce spending, in particular when multiple ACOs are present in the same market and collectively driving down regional spending. The proposal that interested parties have floated for mitigating ACO effects on their region—effectively removing ACO assigned beneficiaries from the regional calculation—has multiple problems that would increase program spending. It would amplify the benefit to ACOs for selecting lower cost patients and avoiding higher needs groups, it would

[546] McWilliams JM, et al. Medicare Spending After 3 Years of the Medicare Shared Savings Program. *New England Journal of Medicine.* Sept. 2018. 379:1139–1149. DOI: 10.1056/NEJMsa1803388.

drive market consolidation, and it would still fail to mitigate the cited problem for cases where multiple ACOs work in combination to drive down regional spending. Furthermore, it would increase program spending to such a degree that compliance with the requirements of section 1899(i)(3) of the Act, to use other payment models, would be violated.

We acknowledge a potential elevated risk; however, that uncertainty around external conditions related to the end of the PHE for COVID–19 and economic conditions like emerging inflation could cause a prospective trend to differ materially from actual program-wide growth in per capita spending. Blending the ACPT as one-third of the overall update helps lower the risk that projection error would create problems with appropriateness of spending targets. Risk-bearing ACOs would have extra protection against exposure to ACPT projection error because they would be held harmless on the downside if the new method would charge them more in losses than the prior retrospective trend method. Modeling indicates this safeguard would reduce shared losses owed by ACOs by about $100 million over 10 years, but the net impact of this provision is likely to save several times that amount by retaining ACOs that would have otherwise dropped out of the program.

The most important factor returning the program to net savings is attracting more ACOs into the BASIC track that serve higher spending populations, particularly low revenue physician-led ACOs for whom a 40 percent sharing rate is a strong incentive for efficiency even absent downside risk. The most important provision for growing this participation is the proposal to allow ACOs to stay sharing only (that is, Level A or Level B of the BASIC track) for a full 5-year agreement period. Advance investment payments and partial shared savings payments for savings under the MSR would help to increase the share of these new ACOs that are low revenue. These exclusive provisions for low revenue ACOs are estimated to drive $3 billion in net savings over the projection period notwithstanding marginal increases in shared savings outlays. This analysis highlights that the savings gained from increasing participation from this type of ACO would greatly exceed the marginal increase in program outlays from paying partial shared savings under the MSR and advance investment payments, as combined incentive payments (consisting mainly of shared savings payments combined with slightly higher payments to clinicians achieving QP status) to new and reentering ACOs are only projected to reach about 1.1 percent of benchmark over the projection period in return for savings on benefits of 2.7 percent (as detailed in Table 141).

Another key proposal for improving the financial impact of the program is establishing a separate ratebook to calculate county-level expenditures for ACOs selecting prospective assignment using an assignable population of beneficiaries that is identified based on the offset assignment window. This proposal would remove a bias that would otherwise artificially boost benchmarks and thereby account for $3.7 billion of the total savings projected above. Most existing ACOs currently benefiting from this bias would still expect to receive favorable regional adjustments at rebasing despite removal of the bias. The proposal to adjust benchmarks for prior savings would help restore a positive benchmark adjustment for the subset of ACOs for whom removal of the prospective assignment bias would minimize their regional adjustments at rebasing. However, because the prior savings adjustment would only be applied if it produced a higher adjustment than the regional benchmark adjustment, it would not further increase benchmarks for ACOs already benefiting from the existing regional adjustment.

Modifications to the quality scoring system through the proposal to add a sliding scale approach to determining shared savings for ACOs to allow for payment of scaled shared savings and the proposal to award health equity bonus points to ACOs that perform well on at least one or more measures while serving a high proportion of duals or beneficiaries in areas with high Area Deprivation Index scores may increase shared savings payments marginally overall depending on how ACOs may otherwise have progressed in future years against what is still a relatively new quality rubric. The costs of adding these new methods for improving scores and paying scaled shared savings are projected to add about $1.3 billion in program spending over 10 years. Other proposals related to assignment and risk adjustment are expected to have relatively nominal financial impacts on the program.

f. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: allowing for advance investment payments; the proposed modifications to the loss sharing rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard; use of the ACPT/national-regional three-way blended benchmark update factor; expanding the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act; and exclusion of the proposed new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program. These proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

A comparison was constructed between the projected impact of the payment methodology that incorporates all proposed changes and a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority. The hypothetical baseline was assumed to be limited to a 50 percent upside-only track rebased every three years but including adjustments allowed under section 1899(d)(1)(B)(ii) of the Act including the up to 50 percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark (capped on the upside or downside as detailed in this proposed rule) and the prior savings adjustment if producing a higher benchmark (also as detailed in this proposed rule). The stochastic model and associated assumptions described previously in this section were adapted to reflect a marginally reduced participation from low-revenue ACOs

because the hypothetical baseline would lack advance investment payments and partial shared savings payments for certain BASIC track ACOs with savings under their MSR. Such analysis estimated approximately $4.9 billion greater average net program savings under the alternative payment model (with the modifications proposed in this proposed rule) that includes all policies that require the authority of section 1899(i)(3) of Act than would be expected under the hypothetical baseline in total over the 2023 to 2034 projection period.

Participation in performance-based risk in the ENHANCED track and the higher levels of the BASIC track is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to the assumptions used in the modeling of the impacts, described previously). Such added savings are partly offset by lower participation associated with the requirement to transition to performance-based risk. Despite the higher maximum sharing rate of 75 percent in the ENHANCED track under the alternative payment model that includes all policies adopted under section 1899(i)(3) of the Act, relative to the 50 percent maximum sharing rate assumed for the single one-sided risk track under the hypothetical baseline, shared savings payments are expected to be reduced relative to the hypothetical baseline because of lower expected participation resulting from the eventual requirement to transition to risk in the second agreement period under the BASIC track and generally more accurate benchmarks due to the incorporation of regional factors into the calculation of benchmark updates for all ACOs.

We will reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

8. Medicare Part B Payment for Preventive Vaccine Administration Services

In section III.H.2.c of this proposed rule, for CY 2023 we are proposing to annually adjust the payment amount for administration of preventive vaccines to reflect geographic locality cost differences. That is, we propose to use the Geographic Adjustment Factor (GAF) described in § 414.26 to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas. Additionally, in section III.H.2.d of this proposed rule, for CY 2023 we are proposing to annually update the payment amount for the administration of preventive vaccines based upon the Medicare Economic Index (MEI). In section III.H.3.c. of this proposed rule, we are proposing to continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under the certain circumstances. Further, we are proposing to adjust and update the $35.50 by the GAF and MEI as we proposed for the preventive vaccine administration services.

The estimated impact of the proposal to update the payment amount for the administration of preventive vaccines based upon the proposed MEI (3.8%) in CY 2023 is an increase in spending of roughly $40 million. Approximately $30 million of the increase is for administration of the COVID–19 vaccine and the remaining $10 million is for the other preventive vaccines. Regarding the proposal to adjust the payment amount for the administration of preventive vaccines by the GAF and the proposal to continue the additional payment for at-home COVID–19 vaccinations, these would have a negligible impact on Medicare spending.

9. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

In section III.I. of this proposed rule, we propose to clarify § 410.40(e)(2)(ii) by reorganizing existing language and stating that the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is required. We are also clarifying that the PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance. Finally, we are clarifying that coverage includes observation or other services rendered by qualified ambulance personnel. While we believe that clarification of the regulatory provisions is needed and would be well received by interested parties, we do not believe that these clarifications would have any substantive monetary or impact the amount of time needed submit claims. We believe the primary benefit of the clarification would be for providers and suppliers in preparing and submitting claims. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

10. Medicare Provider and Supplier Enrollment Changes—Provider Enrollment

a. Expansion of Revocation Reasons

As explained in section III.J. of this proposed rule, we propose changes to two of our existing revocation reasons:

- We propose to expand § 424.535(a)(2) to permit revocation based on an OIG exclusion of the provider's or supplier's managing organization, corporate officer, or corporate director.
- We propose to expand § 424.535(a)(3) to permit revocation based on a felony conviction of the provider's or supplier's managing organization, corporate officer, or corporate director.

We believe these two changes would result in an increase in the number of revocations that CMS imposes. However, we believe this number would be rather small. We currently impose only a limited number of revocations under §§ 424.535(a)(2) and (a)(3). Accordingly, since our expansion of these revocation reasons would be fairly modest, we do not foresee more than a very slight increase in revocations thereunder.

Table 143 outlines the number of revocations we estimate would ensue under our proposed revocation expansions. These numbers only account for additional revocations stemming from our changes:

TABLE 143: Additional Revocations

Revocation Reason	Number
§ 424.535(a)(2)	5
§ 424.535(a)(3)	5
Total	**10**

Internal CMS data indicates that the average provider/supplier that would be affected by these regulatory expansions receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in the CY 2022 PFS final rule) (86 FR 64995)). Providers/suppliers revoked under our proposed revocation expansions would thus not receive these payments. Hence, multiplying our $50,000 estimate by the revocation totals in Table 143 results in a projected transfer from these providers/suppliers to the Federal Government of $500,000 ($50,000 × 10 revocations).

b. Expansion of Fingerprinting Requirements

We propose the following three revisions to § 424.518:

- Adding changes of ownership and the reporting of a new owner as provider enrollment transactions falling within the scope of § 424.518. (As explained in section III.J. of this proposed rule, affected parties would have to submit fingerprints and be subject to a fingerprint-based criminal background check (FBCBC) if the provider or supplier is in the ''high'' level of categorical screening.)
- Stating that any screening level adjustment to ''high'' also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier that originally triggered the screening level increase.
- Moving SNFs from the ''limited'' level of categorical screening to the ''high'' screening level.

These proposed changes would result in an increase in the annual number of providers and suppliers that must furnish fingerprints for their 5 percent or greater direct or indirect owners. Based on existing enrollment statistics and our experience, we project that: (1) 29,726 providers and suppliers per year would be required to submit the fingerprints of their owners (new or existing) pursuant to these changes; and (2) 29,726 owners would annually be fingerprinted (or one owner per provider/supplier, which is roughly consistent with prior estimates).

Consistent with previous burden estimates we have made regarding fingerprinting, we estimate that it would take each owner approximately 2 hours to be fingerprinted. According to the most recent BLS wage data for May 2021, the mean hourly wage for the general category of ''Top Executives'' (the most appropriate BLS category for owners) is $57.94. With fringe benefits and overhead, the figure is $115.88. This would result in an estimated annual burden involving our proposed changes to § 424.518 of 59,452 hours at a cost of $6,889,298.

c. DME Payment Denials

We are also proposing to add a new DMEPOS condition of payment to § 424.57(b). It would require the DMEPOS supplier to be in compliance with all conditions of payment in § 424.57(b), as well as with the licensure requirements of § 424.57(c)(1)(ii)(A), at the time the item or service is furnished in order to receive payment. Based on data collected from our experience with the scenario our proposed change seeks to remedy, we project 6,100 claim denials per month associated with our proposal involving $1.3 million in denied/unpaid claims. Over a 12-month period, this results in 73,200 claim denials and $15.6 million in unpaid claims, the latter constituting our estimated annual transfer to the federal government. We welcome comments on this estimate.

11. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

We do not anticipate any additional costs or savings associated with our proposed revision to § 455.107(b), for the latter merely involves giving the states somewhat greater flexibility in executing the provisions of § 455.107.

12. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.M. of this proposed rule, we are proposing to extend the existing compliance action of sending letters to non-compliant prescribers from the CY 2023 EPCS program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 year (January 1, 2024 through December 31, 2024). Additionally, effective January 1, 2023, we are proposing to change the year from which PDE data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions (§ 423.160(a)(5)(ii)). We are also proposing to determine whether a prescriber qualifies for the emergency or disaster exception (§ 423.160(a)(5)(iii)) based on the prescriber's valid address in PECOS (Medicare Provider Enrollment, Chain, and Ownership System), instead of the NCPDP Pharmacy Database address, and for prescribers who are not enrolled or do not have a valid PECOS address, we are proposing to use the address in the National Plan and Provider Enumeration System (NPPES) data. We understand that with continuing the compliance action of sending letters to non-compliant prescribers for another year, some prescribers may delay EPCS implementation, but we also believe that our education and outreach with these prescribers during this additional year may help increase adoption. We do not anticipate these proposals to have any incremental impact on the cost or time associated with prescriber compliance of the electronic prescribing for controlled substances requirement or the cost to interested parties. However, we acknowledge there will be a delay in compliance enforcement by an additional year. We seek comment on our impact assumptions.

13. Medicare Ground Ambulance Data Collection System

In section III.K. of this proposed rule, we propose a series of changes to the Medicare Ground Ambulance Data Collection System including the proposal to update § 414.626(d)(1) and (e)(2) to give us the necessary flexibility to specify how ground ambulance organizations should submit the hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational, and proposed revisions to

the Medicare Ground Ambulance Data Collection Instrument.

The changes and clarifications aim to reduce burden on respondents, improve data quality, or both. We group our proposed changes and clarifications into four broad categories: editorial changes for clarity and consistency; updates to reflect the web-based system; clarifications responding to feedback from interested parties questions and testing and typos and technical corrections.

While we believe that these changes and clarifications will be well received by the ground ambulance interested parties, we do not believe that these changes would have any substantive impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. We note that the overall length of the Medicare Ground Ambulance Data Collection Instrument would be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we propose to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

14. HCPCS Level II Coding for Wound Care Management Products

We are proposing several changes to our policies for skin substitute products. Specifically, we are soliciting feedback on our key objectives related to skin substitute policies, proposing to change the terminology of skin substitutes to more accurately reflect how clinicians use these products, and to treat and pay for these products under section 1861(s)(2)(A) of the Act as incident to supplies the PFS beginning on Jan 1, 2024. Our estimates related to revising the benefit category to incident to supplies will be contained in the CY 2024 PFS rulemaking.

Additionally, in section III.N. of this proposed rule, we are proposing to revise our HCPCS coding procedures, the impacts related to these proposals are in section III.N. The financial impact of this proposal will be largely contingent on the prices the MACs set for these products.

15. Effects of Proposals for Medicare Part A and B Payment for Dental

In section II.L.2. of this proposed rule, we are: (1) proposing to clarify our interpretation of section 1862(a)(12) of the Act, and clarify and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposing and seeking comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup and certain diagnostic and treatment services prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services; and (3) requesting comments on other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services.

If finalized, we do not believe the proposed codification of current payment policy would result in a significant payment impact because it would be a continuation of existing Medicare payment policy. If we were to finalize the payment for an oral or dental examination, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, we do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of organ transplant, cardiac valve replacement and valvuloplasty surgeries.

To complete this analysis, and to ensure that we captured dental services that occurred prior to the covered medical service that occurred within CY 2019, we pulled claims data for which Medicare made payment for dental services from June 1, 2018 through December 31, 2019. This allowed us to capture any dental services that were furnished prior to 90 days of a covered medical service. Further, we believe that the use of these claims data would be more representative of future utilization patterns given the COVID–19 PHE. Based on this analysis, we estimated that there were roughly 200,000 additional services where Medicare could provide payment for dental services prior to organ transplants, cardiac valve replacement or valvuloplasty surgeries. Based on claims data from this time period, Medicare provided payment for dental services for 186 patients with an average cost of care of roughly $525 per person. The majority of these claims were for tooth extraction in patients undergoing radiation treatment of the mouth as opposed to transplant patients, and the range in costs was from $33 to $5,711 per patient. Based on a review of claims data for our existing payment policies and our review of current utilization for beneficiaries, we estimated that effective rate of coverage of current utilization was less than 0.2 percent. We then used this utilization ratio to estimate projected payments for dental exams and treatments prior to organ transplants, cardiac valve replacement or valvuloplasty surgeries. Given current utilization of organ transplants, cardiac valve replacement or valvuloplasty procedures, current utilization and payment for dental exams and treatments, we are projecting an estimated cost of this proposal at approximately $65 million or roughly 0.07 percent of Medicare PFS expenditures. Therefore, we do not anticipate a significant payment impact for these proposals. We note, however, that if we were to finalize, as discussed in section II.L.2.c.(i) of this proposed rule, payment in other clinical scenarios for dental services inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we may adjust this estimate. We further note that we have requested public comment on alternative ways to estimate the expected utilization and volume of these services under the proposal discussed further in section II.2.c. of this proposed rule.

16. Updates to the Quality Payment Program

In this section, we estimate the overall and incremental impacts due to the Quality Payment Program policies proposed in this rule. We estimate participation, final scores, and payment adjustment for clinicians participating through traditional MIPS, MVPs, and the APM. We also present the incremental impacts to the number of expected QPs and associated APM Incentive Payments that result from our proposed policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall MIPS Modeling Approach and Data Assessment

(1) Updating the MIPS Model

We created two MIPS RIA models: a baseline and proposed policies RIA model. The aim of the baseline model is to reflect participation, final scores, and payment adjustments for the CY 2023 performance period/2025 MIPS payment year based on previously finalized policies for the CY 2023 performance period/CY 2025 MIPS payment year. Examples of previously finalized policies are an increase in the APM qualified participants threshold

and the removal of the additional MIPS payment adjustment for exceptional performance and additional performance threshold. The proposed policies model builds off the baseline model and incorporates the MIPS policy proposals for the CY 2023 MIPS performance period/2025 MIPS payment year included in this rule. The aim of the proposed policies model is to estimate the incremental impacts of the proposed policies in this proposed rule. There were two major updates to the modeling approach used in this RIA.

First, we changed the MIPS modeling tool that we used in order to incorporate the same scoring engine as the one used to determine actual MIPS payment adjustments. We generally applied the same assumptions as our previous RIA analyses, but this update ensures that the clinician population and final scores in our model align as much as possible with actual MIPS scoring and minimizes differences between projections and policy implementation. It should be noted, data limitations and assumptions which may impact model results still remain and are described below.

Second, we modeled participation, scoring, and payment adjustments for the MIPS Value Pathways (MVPs). The CY 2023 performance period/2025 MIPS payment year is the first year where clinicians can voluntarily submit MVPs. Although we are modeling MVPs, we are not modeling subgroup reporting. A more detailed discussion of the approach used to model MVPs can be found in section VII.E.16.d.(2) of this RIA.

(2) Assessing Which Data To Use To Estimate Future MIPS Performance

This RIA uses the 2019 MIPS performance period submissions that were used for the CY 2022 PFS final rule RIA (86 FR 65617 through 65660). We discussed in the 2022 PFS final rule (86 FR 65637), how we assessed the use of 2020 performance period submissions and why we believed the 2019 performance period submissions would be a better data source, for the purposes of estimating future performance for the entire population of MIPS eligible clinicians. The submissions for the 2021 MIPS performance period were not available in time to assess whether the data can be used to predict future performance. For the final rule, we will evaluate whether it is appropriate to use the 2021 performance period data and whether adjustments would need to be made if CY 2021 performance category submissions data were used. For these reasons, we again used CY 2019 data to estimate the MIPS eligible clinician population and their associated final scores for the CY 2023 MIPS performance period/CY 2025 MIPS payment year.

b. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2024, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs in the applicable QP Performance Period for a year and the corresponding payment year. These QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to the MIPS reporting requirements and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B covered professional services in a payment year based on performance during a prior performance period.

We incorporated this change into our baseline eligibility determination. In addition, the thresholds to achieve QP status beginning in the 2023 QP Performance Period will increase to 75 percent for payment amount, and 50 percent for patient count. Overall, we estimate that for the 2023 QP Performance Period between 144,700 and 186,000 eligible clinicians would become QPs, and therefore be excluded from MIPS.

In section VII.F.17.a. of this proposed rule, we projected the number of eligible clinicians that would be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that would be operating during the 2023 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2023 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2023 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Kidney Care First; Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Basic Track Level E, and the ENHANCED Track);
- Primary Care First (PCF) Model;
- Radiation Oncology Model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) on the 2021 third snapshot participation file to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2023 QP Performance Period. We examined the extent to which Advanced APM

participants would meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Estimated Number of Clinicians Eligible for MIPS for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

For the baseline and proposed policies models, we generally used the same eligibility files, assumptions, and rules as described in the CY 2022 PFS final rule (86 FR 65639 through 65642), with the following updates:

- We used the eligibility determination file that aligned with the performance period of our submission data. Previously, in the CY 2021 PFS final rule (85 FR 85013), we noted we used a combination of data from the first determination period for the 2020 MIPS performance period (from October 1, 2018 to September 30,2019) and data from the end of calendar year 2019 (from October 1, 2019 to December 31, 2019). We additionally noted that we used the determination period from the 2020 MIPS performance period eligibility file because it was the most recent eligibility file available. As we updated our model, we now believe using the final eligibility file from 2019, which reconciles information from the two eligibility determination periods would be a better data source to pair with our performance period submission data.
- Our new RIA models, based off of actual MIPS submissions and scores estimates scores for clinicians for NextGen ACOs and CPC+ (which were previously excluded from our CY 2022 PFS final rule RIA models (citation). The NextGen ACOs and CPC+ are both no longer available in the CY 2023 MIPS performance period, but we included these participants in our models because they comprised 18,892 MIPS eligible clinicians who we assume would continue to participate in MIPS.
- We incorporated the QP thresholds for the 2025 payment year as defined at § 414.1430.

We are not proposing any modifications to eligibility, therefore our eligibility assumptions apply to both the baseline and proposed policies models. Our analysis resulted in 1.6 million clinicians who had PFS claims from October 1, 2018 to September 30, 2019 as well as additional clinicians associated with a group who had at least one PFS claim from October 1, 2019 through December 31, 2019.

(2) Estimation of MIPS Eligible Clinicians After Applying Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted to MIPS. A clinician or group that exceeds at least one, but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

We describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians for the proposed policies model. We applied the same assumptions presented in the CY 2022 PFS final rule RIA (86 FR 65617 through 65660) to apply the low-volume threshold and to determine whether clinicians participate as a group, virtual group, APM entity, or as individuals. Table 144 summarizes our eligibility estimates for the proposed policies model. We identify approximately 198,250 clinicians as having ''required eligibility.'' These clinicians will be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. These clinicians may ultimately choose to participate in MIPS as an individual, group, virtual group or APM entity or to not participate. Regardless of participation method, these clinicians will be considered MIPS eligible. We estimate approximately 646,749 MIPS eligible clinicians as having ''group eligibility'' in Table 144. These clinicians belong to a group or virtual group that meets the low-volume threshold and submits to MIPS. If they were not associated with the group or virtual group submission, these clinicians would not be eligible for MIPS. Finally, we estimate about 10,933 clinicians will be eligible through ''opt-in eligibility'' through the ''opt-in'' policy for a total MIPS eligible clinician population of approximately 865,116. This leads to an associated $6.8 billion allowed PFS charges estimated to be included in the CY 2023 performance period/2025 MIPS payment year.

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TABLE 144: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the CY 2023 PFS Proposed Rule Assumptions**

		CY 2023 PFS Proposed Rule Estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	179,322	$45,466
	Do not participate in MIPS	18,928	$ 4,686
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	646,749	$ 17,166
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	10,933	$ 574
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		*865,116	$ 67,899
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	424,752	$10,063
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	107,995	$ 694
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	207,477	$ 9,880
Total Number of Clinicians Not MIPS Eligible		740,224	$ 20,637
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,596,340	$ 88,536

* Estimated MIPS Eligible Population

** This table does not include clinicians impacted by the automatic extreme and uncontrollable policy prior to the PHE for COVID-19. (Approximately 6,000 clinicians and $527 million in PFS allowed charges.)

*** Allowed charges estimated using 2019 dollars. Low-volume threshold is calculated using allowed charges.

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Furthermore, we estimate there would be approximately 424,752 clinicians who are not MIPS eligible, but could be if the clinician or their group elects to opt-in. We describe this group as ''Potentially MIPS eligible'' in Table 144. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1,280,868 clinicians. Finally, we estimate approximately 107,995 clinicians would not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 207,477 would not be MIPS eligible because they are categorically excluded regardless of volume or submission activity.

Eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the 2023 MIPS performance period is closed. For the remaining analysis, we use the estimated population of 865,116 MIPS eligible clinicians described above.

d. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Summary of Approach for MVPs, Traditional MIPS and APM Performance Pathway

In sections IV.A.3.a. through IV.A.3.F. of this proposed rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.E.16.d.(3) of this RIA as we describe our methodology to estimate MIPS payments for the CY 2023 performance period/2025 MIPS payment year. We then present the impact of the overall proposed policies on the CY 2023 performance period/2025 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2023 performance period/2025 MIPS payment year. By comparing the baseline model to the proposed policies model, we are able to estimate the incremental impact of the proposed policies for the CY 2023 performance period/2025 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, and MIPS eligible clinicians can participate as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway or through an MVP in the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity but are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. As discussed in section VII.E.16.a.(2) of this RIA, we generally used the most recently available submissions data from the Quality Payment Program, however, due to the automatic extreme and uncontrollable policy applied in the CY 2020 performance period, for the purposes of this RIA we used data submitted for the CY 2019 MIPS performance period. In the final rule, when data from the CY 2021 performance period will be available, we will revisit this decision. The average percentage change in total revenues that clinicians earn is less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact for MIPS Value Pathways

In the 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MVPs beginning in the CY 2023 MIPS performance period/2025 MIPS payment year. In updating our MIPS RIA model, we have made some assumptions for both the baseline and proposed policies model to simulate MVP participants and their MVP final score which are described in the following sections.

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup or APM entity) to register prior to submitting an MVP. As we do not yet have information on who will register, we assume for purposes of this model, that MVP Participants are individual clinicians or groups that currently submit at least 4 quality measures that are in an MVP. For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the scoring hierarchy as finalized in the CY 2022 PFS final rule 86 FR 65537). For the baseline model, we looked for the quality measures finalized for MVPs in the 2022 PFS final rule (86 FR 65441 through 65443):

- Advancing Rheumatology Patient Care
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes
- Advancing Care for Heart Disease MVP
- Optimizing Chronic Disease Management MVP
- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine
- Improving Care for Lower Extremity Joint Repair
- Patient Safety and Support of Positive Experiences with Anesthesia MVP

For the proposed policies model, we incorporate the proposed quality measure revisions for the above MVPs and use the quality measures to model scores for the new MVPs as proposed in Appendix X of this proposed rule:

- Advancing Cancer Care
- Optimal Care for Kidney Health
- Optimal Care for Neurological Conditions
- Supportive Care for Cognitive-Based Neurological Conditions
- Promoting Wellness

Our MVP Participant assumptions have limitations: we are not incorporating subgroups due to lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we seek comment on this assumption.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to rules finalized in § 414.1365(d) and § 414.1365(e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the 2019 MIPS performance period (upon which our model is based.) Therefore, we scored any improvement activities the MVP Participants submitted in 2019 as if those improvement activities are in the MVP inventory.

(3) Methodology To Assess Impact For Traditional MIPS

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the CY 2019 MIPS performance period submissions data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories. We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, testing data for the revised total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) clinician measures which were finalized in the CY 2020 PFS final rule (84 FR 62969 through 62977), testing data for the new episode cost measures, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2023 performance period/2025 MIPS payment year for the baseline and proposed policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where

each are described in detail in the following sections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2022 PFS final rule (86 FR 65642 through 65643) for the baseline and proposed policies RIA models for the CY 2023 MIPS performance period/2025 MIPS payment year.

To create the baseline policies RIA model, which does not reflect the proposed policies for the CY 2023 performance period/2025 MIPS payment year, we made the following modifications to the CY 2022 PFS final rule finalized policies model to reflect the previously finalized quality performance category policies for the CY 2023 performance period/2025 MIPS payment year:

- As discussed in the CY 2022 PFS final rule (86 FR 65440), we finalized the removal of Web Interface measures after the CY 2022 performance period/2024 MIPS payment year for groups and virtual groups using the existing 10 CMS Web Interface measures. To estimate a quality performance category score for clinicians in groups who previously used the CMS Web Interface as a collection type in 2019, we assumed these groups will use the other two other collection types (MIPS CQMs and eCQMs) available in the CY 2023 performance period/2025 MIPS payment year. We then applied the same methodology described in the CY 2021 PFS proposed rule using CY 2019 MIPS submissions data when the removal of Web Interface as a collection type was previously proposed (85 FR 50387 through 50388).
- As discussed in the CY 2022 PFS final rule (86 FR 65497 through 65498), we finalized removing the 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points starting with the CY 2023 performance period/2025 MIPS payment year. We implemented these changes. Due to technical limitation we were not able to simulate the removal of the special scoring policy of scoring 3 points for class 2 measures for clinicians not in a small practices beginning with the CY 2023 performance period/2025 MIPS payment year. We note that this limitation does not change our findings regarding the incremental impact of our proposed polices since it is a change that effects both the baseline and proposed policies models.
- In the CY 2022 PFS final rule (86 FR 65429), we also finalized extending the use of the CMS Web Interface as a reporting option under the APM Performance Pathway into the CY 2024 MIPS performance period/2026 MIPS payment year. Under this policy, for the CY 2023 MIPS performance period/2025 MIPS payment year, Web Interface reporting would work in the same manner as for the CY 2021 MIPS performance period/2023 MIPS payment year, where ACOs would have the option of reporting either the CMS Web Interface, the APP eCQM/MIPS CQM measure set, or both. In this baseline model, we calculated both a quality performance category score assuming APP submitted measures and another using Web Interface measures and took the highest score. To estimate a quality performance category for APP measures, we used the same methodology described in the CY 2021 PFS proposed rule when the Web Interface was not included in the APP (85 FR 50388).
- Similar to the CY 2022 PFS final rule model (86 FR 65642), we utilized the most recent benchmark file: the CY 2021 MIPS performance period historical benchmarks; however for this baseline model, we calculated a performance period benchmark if a historical benchmark was not available.

For the proposed policies model, we made the following modifications to the baseline model to reflect the newly proposed quality performance category policies for the CY 2023 MIPS performance period/2025 MIPS payment year:

- As discussed in section IV.A.10.d.(1)(b)(i) of this proposed rule, we proposed to score administrative claims quality measures using a benchmark calculated from the performance period data. To simulate this policy in our proposed policies model, we used CY 2019 performance period data to score administrative claims measures.
- In Appendix 1 of this proposed rule, we added 9 new MIPS quality measures, removed 15 MIPS quality measures, partially removed 2 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs, and proposed 75 substantially modified MIPS quality measures. Consistent with prior rules, (83 FR 50053), our RIA estimates assume that clinicians who reported Medicare Part B claims, eCQM, MIPS CQM and QCDR measures that are removed would find alternate measures; therefore, we assign points to the measures that were submitted and included them in our scoring model.
- In Appendix A, we propose one new administrative claims measure, Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System, for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities that include at least 1 cardiologist. We included the test data for this measure into our model but we were not able to implement this model into our RIA estimation.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a similar methodology described in the CY 2022 PFS final rule (86 FR 65643) for the baseline and the proposed policies RIA models described in this section.

The baseline policies RIA model used the same methodology as the finalized policies model in the CY 2022 PFS final rule (86 FR 65643) since there are no previously finalized cost performance category policies that will apply beginning with the CY 2023 MIPS performance period.

In section IV.A.10.c.(2)(b) of this proposed rule, we are proposing to revise the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) clinician cost measure as a care episode group. This recategorization of the MSPB measure does not affect the scoring of the cost performance category. Additionally, in section IV.A.10.d.(1)(c)(i) of this proposed rule, we are proposing to establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year. Due to data limitations, we do not have multiple years of cost measures to model improvement scoring. Therefore, we did not make any modifications between the proposed policies and baseline model for the cost performance category scoring.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

For the baseline model, we estimated the facility-based score using the scoring policies finalized in the CY 2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169) incorporating the change to the facility-based scoring hierarchy described in the CY 2022 PFS final rule (86 FR 65526 through 65527). In our proposed policies model, we included two changes to facility-based scoring:

• As discussed in section IV.A.10.d.(2)(b)(i)(A) of this proposed rule, virtual groups would be able to receive a facility-based score.

• Additionally, as discussed in section IV.A.10.d.(2)(a)(i) of this proposed rule, facility-based clinicians would be eligible to receive a complex patient bonus.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

For the baseline RIA model, we used the CY 2019 MIPS Promoting Interoperability performance period submissions data to estimate CY 2023 MIPS performance for the Promoting Interoperability performance category. We did not make modifications to the Promoting Interoperability performance category baseline RIA model beyond what we finalized in the CY 2022 final rule (86 FR 64996).

For the proposed rule model, we considered the following policy proposals as potential modifications to the baseline RIA model:

• Require and modify the Query of PDMP measure for MIPS eligible clinicians participating in the Promoting Interoperability performance category and maintain the associated points at 10 points.

• Expand the Query of PDMP measure to include not only Schedule II opioids but also Schedule III, and IV drugs.

• Change the scoring for the e-Prescribing measure to 10 points available and the maximum total points available for the Electronic Prescribing Objective would remain at 20 points for CY 2023.

• Adding Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure as an optional alternative measure in the Health Information Exchange (HIE) objective.

• Modify the scoring methodology for the Promoting Interoperability performance category . We refer readers to section IV.A.10.c.(4) of this proposed rule, Table 87: Scoring Methodology for the Performance Period in CY 2023 of this proposed rule for further information on the scoring.

• Consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective

• Removing the automatic reweighting of NPs, PAs, CRNAs, or CNSs.

Due to limitations in our scoring engine-based model, we are unable to fully incorporate all of these changes into the proposed policies model. We incorporated into the model the modification to the scoring methodology for the Promoting Interoperability performance category and the removal of the automatic reweighting of NPs, PAs, CRNAs, and CNSs. We continue to use the scores for the e-Prescribing measure in the model as we only have data for the optional Query of PDMP measure. Due to the high submission rate for the optional measure and the expansion of the availability of PDMPs in all 50 States and several localities, we anticipate that clinicians who do not currently submit this newly required measure would now submit the measure or submit one of the associated exclusions. Because we lack CY 2019 MIPS submissions data for the Enabling Exchange Under TEFCA measure and the Health Information Exchange Bi-Directional exchange measure, previously finalized to be required beginning with the CY 2021 performance period, we only used past reporting on the existing Health Information Exchange Objective measures to estimate CY 2023 Promoting Interoperability performance for the proposed rule model. This may result in underestimating the Promoting Interoperability performance category scores if clinicians chose to report the bi-directional exchange measure for the CY 2021 performance period.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we modeled the improvement activities performance category score based on CY 2019 MIPS performance period data and APM participation identified in section IV.A.10.d.(1)(c)(i) of this proposed rule. For clinicians and groups not participating in a MIPS APM, we used their CY 2019 improvement activities score. We did not model the policy finalized in the CY 2020 performance period (84 FR 62980) to require a minimum threshold of 50 percent of clinicians in a group to complete an improvement activity for the group to receive credit since we did not have data to determine the proportion of clinicians in a group that completed the improvement activity. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section VII.F.17.c.(1) of this proposed rule, we assigned an improvement activity performance category score of 100 percent.

(f) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996). We calculated and applied the separate risk indicator complex patient bonus components methodology with a single overall cap described at section IV.A.10.d.(2).(a) of this proposed rule. In section IV.A.10.d.(2)(a)(ii) of this proposed rule, we propose to allow facility based clinicians to receive a complex patient bonus. We incorporated this change in our RIA policies model.

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and proposed policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2022 PFS final rule (86 FR 65519 through 65524).

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold finalized in

the 2022 PFS final rule (86 FR 65527) of 75 points finalized at § 414.1405. For the proposed policies model, we applied the performance threshold of 75 points proposed in section IV.A.10.e.(2) of this proposed rule. We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Impact of Payments by Practice Size

We noticed minimal changes to the mean and median final score between our baseline and proposed policies model. In our baseline model, the mean and median final scores are 73.63 and 77.48, respectively. In the proposed policies model, the mean final score is 73.57 and the median final score is 77.52. Because these mean and median final scores are so close to our performance threshold of 75, many clinicians are only slightly above or slightly below the performance threshold. For instance, in the proposed policies model, 284,000 clinicians have a final score between 70 and 80 points. We recognize that, because many scores are clustered around the performance threshold of 75, any variation in scoring or submissions data such as the presence of submission data for the Trusted Exchange Framework and Common Agreement (TEFCA) measure and the Health Information Exchange bi-directional exchange measures, discussed in section VII.E.16.d.(3)(d) of this RIA, can have a significant impact on the proportion of clinicians receiving a positive or a negative payment adjustment. Between the baseline and proposed policies model we observe a slight difference in the percentage and distribution of clinicians receiving a negative payment adjustment. Overall, we project 66.5 percent of engaged clinicians [547] would receive a positive or neutral adjustment in our proposed policies model up from 62 percent in the baseline model.

We observe a slight difference in payment adjustments by practice size. Note that in the CY 2021 PFS final rule we did not report the solo clinician's category. This category, which encompasses 21,955 clinicians, has a slightly larger share receiving a negative payment adjustment compared to other practice sizes. We note an increase in the percentage of clinicians receiving a positive or neutral payment adjustment between the baseline and proposed policies model for all practice sizes except for large practices where we see a slight decrease.

Because many clinicians scores are close to the performance threshold, many of these clinician's payment adjustments are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. In our proposed policies model, we project a payment adjustment of negative 9 percent for clinicians with a score of 18 points or below and we project only 3,481 clinicians would receive a score of 18 points or below and thus be subject to the maximum negative payment adjustment.

In our baseline model, the average positive payment adjustment among engaged clinicians is 2.50 percent and the average negative payment adjustment is −1.68 percent. In our proposed policies model, the average positive payment adjustment among engaged clinicians is 2.49 percent and the average negative payment adjustment among engaged clinicians is −1.64 percent. Only 6.84 percent of clinicians receive a score of less than 50 points and therefore a negative payment adjustment of more than 3 percent. Because there is only a slight difference in the proportion of clinicians receiving a negative payment adjustment between the proposed policies and baseline model, we anticipate only a modest change in the amount of funds redistributed due to budget neutrality (from $1 billion to $998 million) and a modest change in the maximum positive payment adjustment from 6.8 percent in the baseline to 6.9 percent in the proposed policies model, however, we recognize that a modest change in final scores could influence the amount of funds available for redistribution.

These findings and proposed policies reflect movement away from the transition policies implemented during the early years of MIPS and how MIPS is focusing on value rather than primarily on engagement. However, a large proportion of those who are non-engaged, or not submitting data to MIPS, are clinicians in small practices. Among those who we estimate would not engage with MIPS, 79.8 percent are in small practices (16,614 out of 20,810 clinicians who do not engage). We intend to continue working with interested parties to improve engagement in MIPS among clinicians in small practices.

We want to highlight we are using 2019 MIPS performance period submissions data to simulate a CY 2023 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2023 performance period/2025 MIPS payment year. This is because the PHE for COVID–19 may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for COVID–19 for the CY 2019 MIPS performance period. Therefore, engagement levels in MIPS for the CY 2023 performance period/2025 MIPS payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the CY 2019 performance period/2021 MIPS payment year, which is associated with a performance threshold of 30 points, and that participation may change since the proposed performance threshold is 75 points.

Finally, the combined impact of negative and positive adjustments as a percent of allowed charges among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS.

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[547] We define engaged MIPS clinicians as those who have submitted data for at least one MIPS performance category or are facility-based.

TABLE 145: Estimated CY 2023 Performance Period/2025 MIPS Payment Year Impact on Total Estimated Allowed Charges by Participation Status and Practice Size**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments as Percent of Allowed Charges***
Proposed policy model among non-engaged clinicians				
1) Solo	8,758	.000%	100.000%	-8.994%
2) 2-15	7,856	.000%	100.000%	-8.994%
3) 16-99	2,552	.000%	100.000%	-8.980%
4) 100+	1,644	.000%	100.000%	-8.723%
Overall	20,810	.000%	100.000%	-8.988%
Proposed policy model among engaged clinicians ****				
1) Solo	21,955	48.750%	51.250%	-1.387%
2) 2-15	106,918	53.487%	-0.986%	46.513%
3) 16-99	215,386	56.052%	-0.894%	43.948%
4) 100+	492,765	66.560%	-0.432%	33.440%
Overall	837,024	61.719%	38.281%	-.791%

*Practice size is the total number of TIN/NPIs in a TIN.

** 2019 data used to estimate CY 2023 performance period/2025 MIPS payment year payment adjustments. Payments estimated using 2019 dollars trended to 2025.

***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

****Includes facility-based clinicians' cost and quality data are submitted through hospital programs.

TABLE 146: CY 2023 Performance Period/2025 MIPS Payment Year Impact on Total Estimated Allowed Charges among Clinicians Who Submit Data by Practice Size for the Baseline and Proposed Policies Models**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive as Percent Allowed Charges***
**Baseline model among clinicians who engage with MIPS ** **				
1) Solo	21,942	48.62%	51.39%	-1.41%
2) 2-15	106,904	52.76%	47.24%	-1.01%
3) 16-99	215,383	55.55%	44.45%	-0.91%
4) 100+	492,765	67.61%	32.39%	-0.44%
Overall	836,994	62.11%	37.89%	-0.80%
Proposed **policies model among clinicians who engage with MIPS****				
1) Solo	21,942	48.78%	51.22%	-1.386%
2) 2-15	106,900	53.50%	46.50%	-.986%
3) 16-99	215,383	56.05%	43.95%	-.894%
4) 100+	492,765	66.56%	33.44%	-.432%
Overall	836,990	61.72%	38.28%	-0.79%

*Practice size is the total number of TIN/NPIs in a TIN.

**2019 data used to estimate CY 2023 performance period /2025 MIPS payment adjustments. Payments estimated using 2019 dollars trended to 2025.

***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

****Includes facility-based clinicians whose cost and quality data are submitted through hospital programs.

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we are proposing several policies that have an impact on burden in the CY 2023 performance period/2025 MIPS payment year. In section VII.E.16.e. of this proposed rule, we outline estimates of the costs of data collection that includes both the effect of proposed policy updates and adjustments due to the use of updated data sources. For each proposal included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 147. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 147: Incremental Burden from Associated Proposed Policies

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Total burden associated with the proposal to continue the policies and ICRs set forth in the CY 2022 PFS final rule into the CY 2023 MIPS performance period/2025 MIPS payment year (as discussed in section V.B.9.p of this proposed rule).	1,476,903	$157,603,546
Burden change for MVP registration ICR due to the proposal of additional MVPs (as discussed in section V.B.9.e.(7)(a)(i) of this proposed rule). *	+684	+$67,223
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the proposal of additional MVPs (as discussed in section V.B.9.e.(4) of this proposed rule). *	-8,719	$922,695
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the proposal of additional MVPs (as discussed in section V.B.9.e.(5) of this proposed rule). *	-9,828	-$1,063,579
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the proposal of additional MVPs (as discussed in section V.B.9.e.(6) of this proposed rule). *	-8,320	-$911,269
Burden change for MVP Quality Submission ICR submissions due to the proposal of additional MVPs (as discussed in section V.B.9.e.(7)(a)(iii) of this proposed rule). *	+14,048	+$1,508,672
Burden change for Promoting Interoperability Submission ICR due to the proposed requirement for clinicians to submit their level of active engagement for the Public Health and Clinical Data Exchange Objective (as discussed in section V.B.9.g.(3) of this proposed rule).	+1,096	+$107,715
Total change in burden due to policy for CY 2023	-11,039	-$1,213,933
Total burden set forth in the CY 2023 PFS proposed rule	1,465,864	$156,389,613

* The total change in burden due to this proposal includes an increase in burden due to an anticipated increase in the number of respondents that would participate in MVP reporting based on the proposed addition of 5 new MVPs. Therefore, there would be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.9.e.(7)(a)(i) of this proposed rule.

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(2) Additional Impacts to Clinicians

(a) MVP Maintenance and Development Process

In section IV.A.8.a. of this rule, we propose updates to the previously finalized policies for the MVP development and maintenance process in the CY 2021 and 2022 PFS final rules (85 FR 84849 through 84856 and 86 FR 65410). Specifically, we propose to modify the MVP development process such that we would evaluate a submitted candidate MVP through the MVP development process and if we determine it is ''ready'' for feedback, we would post a draft version of the MVP on the Quality Payment Program website (*https://qpp.cms.gov/*) and solicit feedback for a 30-day period. Interested parties and the general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we would not notify the interested party who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process.

We also propose that beginning with the CY 2023 performance period/2025 MIPS payment year, to modify the MVP maintenance process such that interested parties and the general public would be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. If we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public, through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and

registration process for the webinar through our Quality Payment Program Listserv.

We acknowledge that there is administrative burden associated with the monitoring and review of the candidate MVPs. However, we are unable to estimate the impact of these proposals and quantify the number of interested parties and members of the general public that would review and submit their feedback for a candidate MVP. Similarly, we are uncertain on the number of interested parties and members of the general public that would submit their recommendations for potential revisions to established MVPs for an applicable performance period and if CMS would be hosting a public webinar based on the review of the recommendations. In summary, we are unable to quantify the impact associated with the proposed changes to the MVP development and maintenance process.

(b) Subgroup Registration

In section IV.A.8.e.(3) of this rule, we propose that as part of the subgroup registration process, in addition to the previously established registration requirements, group TINs must provide a description of each subgroup that is registered. Under this proposed policy, we would identify some key scenarios for subgroups to select from that we expect might reflect a typical subgroup, but also wish to offer an opportunity for group TINs to describe how they constructed their subgroups by providing a narrative in a text-only field, if the options we provide do not correctly describe the subgroup. We recognize that there may be additional burden associated with the proposed description requirement for subgroup registration. However, we assume that the burden associated with choosing a key scenario would minimize the time required for subgroups to provide a narrative description. Additionally, we anticipate the narratives to be short descriptions of the nature of a group practice and appropriately reflect the subgroup composition. We are unable to quantify the additional impact for the proposed subgroup description requirement.

(c) Impact on Third Party Intermediaries

In section IV.A.10.g.(3)(a) of this rule, we propose to revise the corrective action plan (CAP) requirement at § 414.1400(e)(1)(i)(B) to address the impact to any affected parties, as appropriate. We also propose to add § 414.1400(e)(1)(i)(E) to require the detailed communication plan for communicating the issues that contributed to the non-compliance and the impact to any affected parties, as appropriate. We anticipate administrative burden associated with the proposed requirement for third party intermediaries to submit a detailed communication plan. Because of the relatively low number (fewer than 10 per year historically) of CAPs that we anticipate receiving from QCDRs for the CY 2023 performance period/2025 MIPS payment year, we are unable to quantify the burden associated with the development of a communication plan for third party intermediaries.

(d) Compare Tools: Public Reporting

In section IV.A.10.h.(1) of this rule, we propose to identify clinicians who perform telehealth services using Place of Service Code 02 (indicating telehealth) on paid physician & ancillary service (that is, carrier) claims, or modifier 95 appended on paid claims. Additionally, we propose publicly reporting Medicare procedural utilization data on the Compare tool clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions. We would begin publicly reporting procedural utilization data no earlier than CY 2023. We will use a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. While the Compare tool proposals do not increase the burden of collections, we note that the PRA package may require relevant modification to reflect the Compare tool's new uses and public display.

(e) Administrative Claims Measure

As discussed in appendix 1, we are proposing to add one new administrative claims quality measure beginning in the CY 2023 performance period/2025 MIPS payment year and for future performance periods: Risk-standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there are no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(f) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.10.b of this proposed rule, we are proposing changes to the improvement activities inventory for the CY 2023 performance period/2025 MIPS payment year and future years as follows: adding four new improvement activities; modifying five existing improvement activities; and removing six previously adopted improvement activities. We refer readers to Appendix 2 of this proposed rule for further details. We do not believe these proposed changes to the inventory will significantly impact time or financial burden on interested parties because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We recognize that different activities may require differing amount of time to complete, but for the purposes of the COI, we focus on the amount of time it takes to submit the associated information into the system. We do not expect these proposed changes to the inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2023 MIPS performance period.

g. Assumptions & Limitations

In section VII.E.16.d.(4) of this RIA we noted the limitation that, because many scores are clustered near the performance threshold of 75 points, minor variations in clinicians final scores relative to our estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment. In addition to this limitation, we note several other

limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the CY 2023 performance period/2025 MIPS payment year. Due to the PHE for COVID–19, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the CY 2023 performance period/2025 MIPS payment year that we are not able to model with our historic data sources. The scoring model results presented in this proposed rule assume that CY 2019 Quality Payment Program data submissions and performance are representative of CY 2023 Quality Payment Program data submissions and performance. The estimated performance for the CY 2023 performance period/2025 MIPS payment year using CY 2019 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the CY 2019 performance period/2021 MIPS payment year was significantly lower (30 out of 100 points) than the proposed performance threshold for the CY 2023 performance period/2025 MIPS payment year (75 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in in the CY 2019 Quality Payment Program and submitted data would continue to elect to opt-in in the CY 2023 performance period/2025 MIPS payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

There are additional limitations to our estimates In addition to the limitations described throughout the methodology sections: (1) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 144 and (2) our data for the cost performance category does not overlap with CY 2019 so we may not be capturing performance for all clinicians. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we propose to exercise agency discretion, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)

As discussed in section II.B. of this proposed rule, ''(5) PE RVU Methodology,'' Steps 3, 10, and 18, and ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'', we hold the work RVUs constant and adjust the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the Medicare Economic Index (MEI) cost shares are updated, we typically propose to modify steps 3 and 10 described in section II.B. of this proposed rule to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 described in section II.B. of this proposed rule. The most recent recalibration was done for the CY 2014 RVUs, when the MEI was last updated.

As an alternative to adjusting the aggregate pools of direct and indirect PE costs and using a relativity adjustment based on the current CY 2014 MEI update, we considered using the proposed rebased and revised MEI cost share weights for CY 2023, as discussed in detail in section II.M. of this proposed rule, for purposes of adjusting the RVUs to match PE share of the MEI for CY 2023. We considered using the rebased and revised cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, shifting over a 4 year transition to reach the proportions of work, PE, and MP, as proposed in section II.M. of this proposed rule.

Table 148 illustrates specialty-specific impacts for the proposed rule if we were to use the proposed rebased and revised MEI cost share weights to adjust the RVUs to match the PE share of the MEI. Column C represents specialty level impacts of our proposals for CY 2023 without the recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights, shown for comparison to the alternatives considered (same impacts as shown in Table 139). Column E represents the specialty level impacts of our proposals for CY 2023 with Year 1 of a 4-year phased in recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights. Column F represents the specialty level impacts of our proposals for CY 2023 with the recalibration of RVU proportions based on the proposed rebased and revised MEI cost share weights, without a 4-year phase in, but rather, a full implementation for CY 2023.

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TABLE 148: CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty using Rebased and Revised MEI Cost Share Weights as Proposed for CY 2023

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
TOTAL	*TOTAL*	$91,046	0%	0%	0%
	Non-Facility	$61,291	-1%	-1%	2%
	Facility	$29,755	2%	1%	-4%
ALLERGY/IMMUNOLOGY	*TOTAL*	$232	-1%	0%	5%
	Non-Facility	$224	-1%	0%	6%
	Facility	$8	0%	-1%	-6%
ANESTHESIOLOGY	*TOTAL*	$1,743	-1%	-2%	-6%
	Non-Facility	$367	-3%	-3%	0%
	Facility	$1,376	-1%	-2%	-8%
AUDIOLOGIST	*TOTAL*	$70	0%	1%	3%
	Non-Facility	$68	0%	1%	3%
	Facility	$2	0%	-1%	-4%
CARDIAC SURGERY	*TOTAL*	$197	-1%	-3%	-9%
	Non-Facility	$38	-2%	-2%	4%
	Facility	$159	-1%	-3%	-12%
CARDIOLOGY	*TOTAL*	$6,310	-1%	-1%	-1%
	Non-Facility	$4,641	-2%	-2%	1%
	Facility	$1,669	1%	-1%	-7%
CHIROPRACTIC	*TOTAL*	$670	0%	0%	1%
	Non-Facility	$668	0%	0%	1%
	Facility	$1	-1%	-1%	-3%
CLINICAL PSYCHOLOGIST	*TOTAL*	$785	-2%	-3%	-6%
	Non-Facility	$609	-2%	-3%	-5%
	Facility	$176	-2%	-3%	-8%
CLINICAL SOCIAL WORKER	*TOTAL*	$854	-2%	-3%	-6%
	Non-Facility	$656	-2%	-3%	-5%
	Facility	$198	-2%	-3%	-8%
COLON AND RECTAL SURGERY	*TOTAL*	$155	-1%	-2%	-4%
	Non-Facility	$56	-1%	-1%	4%
	Facility	$100	-1%	-2%	-8%
CRITICAL CARE	*TOTAL*	$352	1%	0%	-5%
	Non-Facility	$53	-1%	-1%	2%
	Facility	$298	2%	0%	-6%
DERMATOLOGY	*TOTAL*	$3,758	0%	1%	5%
	Non-Facility	$3,622	0%	1%	5%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
	Facility	$136	0%	-1%	-4%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$822	3%	5%	16%
	Non-Facility	$821	3%	5%	16%
	Facility	$	-1%	-2%	-6%
EMERGENCY MEDICINE	*TOTAL*	$2,531	1%	-1%	-7%
	Non-Facility	$231	-1%	-1%	0%
	Facility	$2,300	1%	-1%	-8%
ENDOCRINOLOGY	*TOTAL*	$532	0%	0%	0%
	Non-Facility	$427	0%	0%	0%
	Facility	$105	3%	2%	-4%
FAMILY PRACTICE	*TOTAL*	$5,786	1%	0%	0%
	Non-Facility	$4,637	0%	0%	1%
	Facility	$1,148	5%	4%	-1%
GASTROENTEROLOGY	*TOTAL*	$1,591	0%	-1%	-3%
	Non-Facility	$604	-1%	-1%	2%
	Facility	$987	0%	-1%	-6%
GENERAL PRACTICE	*TOTAL*	$371	0%	0%	0%
	Non-Facility	$301	-1%	-1%	1%
	Facility	$70	4%	3%	-2%
GENERAL SURGERY	*TOTAL*	$1,760	-1%	-2%	-5%
	Non-Facility	$510	-1%	0%	3%
	Facility	$1,250	-1%	-2%	-9%
GERIATRICS	*TOTAL*	$175	3%	2%	1%
	Non-Facility	$98	0%	0%	0%
	Facility	$78	6%	5%	1%
HAND SURGERY	*TOTAL*	$255	0%	0%	1%
	Non-Facility	$135	0%	0%	2%
	Facility	$120	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,706	-1%	-1%	1%
	Non-Facility	$1,129	-2%	-1%	3%
	Facility	$577	1%	0%	-5%
INDEPENDENT LABORATORY	*TOTAL*	$594	0%	1%	10%
	Non-Facility	$593	0%	1%	10%
	Facility	$	-2%	-2%	-6%
INFECTIOUS DISEASE	*TOTAL*	$586	5%	4%	0%
	Non-Facility	$93	-2%	-1%	2%
	Facility	$493	6%	5%	-1%
INTERNAL MEDICINE	*TOTAL*	$9,813	3%	3%	1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
	Non-Facility	$5,051	0%	0%	0%
	Facility	$4,761	7%	6%	1%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$925	-1%	-1%	1%
	Non-Facility	$730	-1%	-1%	3%
	Facility	$196	0%	-1%	-5%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$465	-3%	-2%	2%
	Non-Facility	$365	-4%	-3%	5%
	Facility	$100	0%	-2%	-9%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$150	0%	0%	-2%
	Non-Facility	$76	-1%	-1%	1%
	Facility	$74	1%	0%	-5%
NEPHROLOGY	*TOTAL*	$2,023	1%	1%	-2%
	Non-Facility	$1,282	-1%	-2%	-2%
	Facility	$741	6%	5%	-1%
NEUROLOGY	*TOTAL*	$1,397	0%	-1%	-1%
	Non-Facility	$942	-1%	-1%	1%
	Facility	$455	1%	0%	-5%
NEUROSURGERY	*TOTAL*	$727	0%	-2%	-8%
	Non-Facility	$131	-1%	-1%	1%
	Facility	$596	0%	-2%	-10%
NUCLEAR MEDICINE	*TOTAL*	$53	-3%	-2%	0%
	Non-Facility	$50	-3%	-2%	0%
	Facility	$3	4%	2%	-4%
NURSE ANES / ANES ASST	*TOTAL*	$1,115	-1%	-2%	-8%
	Non-Facility	$25	-5%	-6%	-11%
	Facility	$1,091	-1%	-2%	-8%
NURSE PRACTITIONER	*TOTAL*	$5,803	2%	1%	0%
	Non-Facility	$3,778	0%	0%	0%
	Facility	$2,024	5%	4%	0%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$593	-1%	-1%	-1%
	Non-Facility	$409	-1%	0%	2%
	Facility	$183	0%	-1%	-7%
OPHTHALMOLOGY	*TOTAL*	$4,838	0%	0%	3%
	Non-Facility	$3,447	0%	1%	4%
	Facility	$1,391	0%	0%	0%
OPTOMETRY	*TOTAL*	$1,308	0%	0%	4%
	Non-Facility	$1,248	0%	1%	4%
	Facility	$60	0%	0%	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$72	-1%	-1%	3%
	Non-Facility	$61	-1%	0%	5%
	Facility	$12	-1%	-1%	-4%
ORTHOPEDIC SURGERY	*TOTAL*	$3,462	0%	-1%	-2%
	Non-Facility	$1,563	0%	0%	3%
	Facility	$1,900	0%	-1%	-6%
OTHER	*TOTAL*	$58	-1%	-1%	2%
	Non-Facility	$47	-2%	-1%	3%
	Facility	$11	0%	0%	-4%
OTOLARNGOLOGY	*TOTAL*	$1,136	0%	0%	2%
	Non-Facility	$903	0%	0%	3%
	Facility	$233	0%	-1%	-5%
PATHOLOGY	*TOTAL*	$1,163	0%	0%	2%
	Non-Facility	$1,138	0%	0%	2%
	Facility	$26	-1%	-1%	-6%
PEDIATRICS	*TOTAL*	$57	1%	0%	-1%
	Non-Facility	$37	-1%	0%	1%
	Facility	$20	3%	2%	-3%
PHYSICAL MEDICINE	*TOTAL*	$1,091	3%	2%	2%
	Non-Facility	$577	-1%	-1%	2%
	Facility	$514	7%	6%	1%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$4,991	-1%	-1%	2%
	Non-Facility	$4,991	-1%	-1%	2%
	Facility	$	-2%	-2%	-6%
PHYSICIAN ASSISTANT	*TOTAL*	$3,168	1%	0%	0%
	Non-Facility	$2,101	0%	0%	2%
	Facility	$1,067	2%	1%	-4%
PLASTIC SURGERY	*TOTAL*	$321	0%	0%	-2%
	Non-Facility	$142	0%	0%	2%
	Facility	$179	0%	-1%	-4%
PODIATRY	*TOTAL*	$1,996	-1%	-1%	2%
	Non-Facility	$1,778	-1%	-1%	3%
	Facility	$218	0%	-1%	-4%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$77	2%	4%	15%
	Non-Facility	$77	2%	4%	15%
PSYCHIATRY	*TOTAL*	$980	2%	1%	-1%
	Non-Facility	$526	-1%	-1%	-1%
	Facility	$454	5%	4%	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
PULMONARY DISEASE	*TOTAL*	$1,397	2%	1%	-1%
	Non-Facility	$585	0%	0%	2%
	Facility	$812	4%	2%	-3%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,608	0%	1%	6%
	Non-Facility	$1,539	0%	1%	6%
	Facility	$69	-1%	-2%	-8%
RADIOLOGY	*TOTAL*	$4,712	-3%	-3%	-2%
	Non-Facility	$4,486	-3%	-3%	-1%
	Facility	$226	0%	-2%	-8%
RHEUMATOLOGY	*TOTAL*	$546	-1%	-1%	1%
	Non-Facility	$489	-1%	-1%	2%
	Facility	$56	0%	-1%	-6%
THORACIC SURGERY	*TOTAL*	$314	-1%	-2%	-8%
	Non-Facility	$65	-3%	-2%	4%
	Facility	$249	-1%	-3%	-11%
UROLOGY	*TOTAL*	$1,754	-1%	-1%	0%
	Non-Facility	$1,258	-1%	-1%	3%
	Facility	$497	-1%	-2%	-7%
VASCULAR SURGERY	*TOTAL*	$1,095	-3%	-2%	1%
	Non-Facility	$810	-3%	-2%	6%
	Facility	$285	-1%	-3%	-12%

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The majority of specialties would experience shifts of 1 percent or greater if we used the proposed rebased and revised MEI cost share weights, as opposed to the current weights, displayed in Table 148, for proportioning work, PE, and MP RVUs. Several specialties shifted by greater than 3 percent, particularly the specialties with relatively higher PE costs, which are mostly realizing a positive shift, or relatively higher physician work costs, which are realizing a negative shift. As shown in Column F, the shifts are amplified, both negatively and positively, when use of the proposed rebased and revised MEI cost share weights is not phased in over several years; therefore, we did not consider this a viable alternative for consideration. We note that there are significant shifts in specialty level payments if we used the proposed rebased and revised MEI cost share weights, some of which counter other CY 2023 proposals (that is, changes to Evaluation and Management (E/M) services, chronic pain management, and behavioral health services).

We have proposed to delay the adjustments to allow public comment and finalization of the proposed rebased and revised MEI, and to maintain use of the current MEI cost share weights while presenting the information in section II.M. of this proposed rule and the specialty level impacts in Table 148. We are also soliciting comment on the use of a transition to phase in use of the proposed rebased and revised MEI cost share weights, if and as finalized, for potential future rulemaking. Because there are significant proposed methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since the last rebasing and revision of the MEI, we believe it is important to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporate the updated MEI into PFS ratesetting, and we believe this is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Similarly, we are proposing to delay the implementation of the proposed rebased and revised MEI for use in the PE geographic practice cost index (GPCI) to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporate the updated MEI into the PE GPCIs.

2. Alternatives Considered for the Practice Expense (PE) Geographic Practice Cost Index (GPCI)

As discussed in section II.G. of this proposed rule, we use the MEI cost share weights to weight the four components of the PE GPCI: employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses. As the MEI cost shares are updated, we have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI. Instead, we are proposing to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 proposed GPCIs, allowing interested parties the opportunity to review and comment on, and for us to respond to comments and finalize, the proposed rebased and revised MEI cost share weights. Because there are significant proposed methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since the last rebasing and revision of the MEI, we believe it is important to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporate the updated MEI into the PE GPCI.

As an alternative to using the current 2006-based cost share weights, we considered using the proposed rebased and revised Medicare Economic Index (MEI) cost share weights for CY 2023, as discussed in detail in section II.M. of this proposed rule for purposes of weighting the four components of the CY 2023 PE GPCI. Specifically, within the four components of the PE GPCI, we considered proposing to update the employee compensation component from 16.553 percent to 24.716 percent, the office rent component from 10.223 percent to 5.893 percent, the purchased services component from 8.095 percent to 13.914 percent, and the medical equipment, supplies, and other miscellaneous expense component from 9.968 percent to 6.819 percent, as shown in Table 149.

TABLE 149: Weighting of the PE GPCI Based on the Cost Share Weights for CY 2023

Expense Category	Current Cost Share Weights	Proposed CY 2023 Cost Share Weights	Rebased and Revised Cost Share Weights as Proposed in Section II.M.
Practice Expense	44.839%	44.839%	51.341%
- Employee Compensation	16.553%	16.553%	24.716%
- Office Rent	10.223%	10.223%	5.893%%
- Purchased Services	8.095%	8.095%	13.914%
- Equipment, Supplies, Other	9.968%	9.968%	6.819%

The use of the proposed rebased and revised MEI cost share weights only impacts the PE GPCI. When the PE GPCI was calculated using the proposed rebased and revised MEI cost share weights, 10 of the 112 PE GPCI values remained the same compared to the calculated PE GPCI using the current 2006-based MEI cost share weights. Three of the 112 PE GPCI values differed by ±0.001 and 68 of the 112 PE GPCI values differ less than or equal to ±0.009. Therefore, the proposal to maintain the use of the current 2006-based MEI cost share weights has little to no effect on over 70 percent of the localities' PE GPCIs. Of the remaining 31 localities with a difference of greater than ±0.009 between the proposed PE GPCI and the alternative considered, 10 realize an increased PE GPCI when the current 2006-based MEI cost share weights were used, ranging from an increase of 0.010 to 0.012, as compared to the PE GPCI if the proposed rebased and revised MEI cost share weights were incorporated. The remaining 21 localities realize a decrease in PE GPCI when the current 2006-based MEI cost share weights were used, ranging from a decrease of 0.010 to 0.028. We note that we are seeking comment in section II.G. of this proposed rule on the proposal to maintain the use of the current 2006-based MEI cost share weights and postpone the implementation of the proposed rebased and revised MEI cost share weights for consideration through potential future rulemaking. See Alternate Addenda D and E to this proposed rule for the CY 2023 GPCIs and summarized GAFs if the rebased and revised MEI cost share weights proposed in section II.M. of this proposed rule, were incorporated to weight the proposed CY 2023 PE GPCIs (for comparison to Addenda D and E with the proposal to maintain the current 2006-based MEI cost share weights for the PE GPCIs). Because the PE GPCIs factor into the GAF equation, we created an Alternate Addendum D to show the recalculated GAFs if the rebased and revised MEI cost share weights were incorporated to weight the CY 2023 PE GPCIs as well. These alternative addenda are available on the CMS website under the supporting documents section of the CY 2023 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. We note that only the PE GPCI and GAF values differ between Addenda D and E, and Alternate Addenda D and E, as the proposed rebased and revised cost share weights do not impact the work or MP GPCIs.

3. Alternatives Considered Related to Payment for E/M Services

In developing our policies for other E/M visits effective January 1, 2023, we considered a number of alternatives. For reasons discussed in our E/M policy section (section II.F. of this proposed rule) we considered several refinements for the RUC-recommended work RVUs for several of the codes in the families based on survey time changes to include Hospital Inpatient or Observation Care, Nursing Facility visits, and Home or Residence Services. We proposed to accept the RUC recommendations for the work RVUs because we believe they are more accurate values. For some of these codes the overall times changed and the RUC recommended work RVUs accurately reflect changes based on changes in the times for the service. For

some of the codes, changes were noted in the total time and intra-service times which was reflected in the intra-time and total time ratios that led to an increase. Given our interest in maintaining continuity in the overall code set, we are proposing to accept the RUC recommendations for the work time values and work RVUs for these codes and are seeking public comment on our concerns for specific codes.

We considered adopting the CPT coding for prolonged services as an alternative but after thoughtful consideration we are proposing to develop Medicare-specific coding (three G-codes, one per setting) to avoid potentially substantial overpayment, provide administrative simplification, enable CMS to determine how much time is being spent with patients using claims data, and facilitate program integrity. Allowing for CMS to determine how much time is being spent with patients using claims data is important for future valuation of services on the PFS, and for program integrity. If we proposed to merely accept the CPT prolonged service coding changes, we would not be able to identify the time spent with patients in the claims data alone, because we might not know which primary service is the companion code to the prolonged service code(s) due to the wide service timespan (for prolonged services without direct patient contact) and non-specific care settings within the prolonged CPT code descriptors. We considered two options in coming to our proposal. First, we considered using the descriptor time plus 15 minutes which would allow for prolonged services to be reportable once the practitioner spends 15 additional? minutes beyond the ceiling time of the primary service. Or, our second option was to use total time plus 15 minutes allowing for prolonged services to be reportable once the practitioner spends 15 additional minutes beyond the total time of the primary service. Both of these options would allow for time to be counted on any day within the survey period with no frequency limit. However, we decided to take the same approach we did for the office/outpatient E/M visits by proposing Medicare specific coding (GXXX1 through GXXX3) for prolonged services for other E/Ms. We proposed to value the G codes similarly to the parallel CPT codes, and require total time to be met before prolonged time starts. Reporting this way, through the use of a G code for each of the specified code families, allows for administrative simplicity and payment accuracy.

4. Alternatives Considered Related to Proposal To Allow Audiologists To Furnish Diagnostic Tests, as Appropriate Without a Physician Order

As discussed in section II.K. of this proposed rule, interested parties have told us that our regulatory requirement for a physician or NPP order for diagnostic audiology services may be impeding access to audiologists. More recently they have requested that we eliminate the treating physician (or NPP) order requirement for the diagnostic hearing and balance assessment services furnished by audiologists—via notice and comment rulemaking—to enable greater access to these services.

As we also discussed in section II.K. of the proposed rule, we are concerned that direct access of audiologists' services, that is the removal of the order requirement for these hearing and balance services furnished by audiologists, might lead to payment for services that are not medically necessary because the results are not being used by a treating physician or NPP in the management of the patient's medical condition. Nonetheless, after careful consideration of the interested parties' requests, we have proposed to amend the regulation at § 410.32(a)(4) to remove the order requirement for certain audiology services furnished personally by an audiologist once per beneficiary per 12-month period for non-acute hearing conditions. We also propose to create HCPCS code GAUDX (*Audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids; may be performed on an annual basis*) to describe audiology services furnished without the order of a treating physician or practitioner.

When developing our proposed policy, we considered adding audiologists to § 410.32(a)(2), under the provision that permits nonphysician practitioners to order diagnostic tests. However, unlike audiologists, the practitioners identified in this provision are all required to accept payment on an assignment-related basis under section 1842(b)(18)(C) of the Act and must accept the Medicare payment amount as payment in full. Medicare payment for audiology services provided by audiologists who do not accept assignment would result in higher out-of-pocket expense (that is, the balance billed amount) than if they did accept assignment. In addition, Medicare Part B does not recognize audiologists to treat or manage patients, unlike PAs, NPs or CNSs who may bill for E/M services, and for whom Medicare Part B covers services and supplies incident to their own professional services as provided in the regulation at § 410.26. Rather, because audiology services furnished by audiologists include only diagnostic hearing and balance assessment services, we concluded that adding audiologists with the NPPs listed in § 410.32(a)(2) was inappropriate.

We also considered alternatively removing the requirement for the order of a treating physician or practitioner for audiology services without the annual limitation. However, we had concerns about the possibility of overutilization of HCPCS code GAUDX if the results of audiology testing are not used by a treating clinician to manage the patient's medical condition. Additionally, we do not have the ability to predict the behavioral response of audiologists to removal of order requirements. Therefore, we believe that adding an annual limitation would serve to address some of our concerns of overutilization. To monitor for the appropriate use of HCPCS code GAUDX, we will establish system edits through our usual change management process to ensure that GAUDX is only paid once every 12 months per each beneficiary. This will also help address program integrity concerns about audiologists billing GAUDX more frequently, furnishing services that are not reasonable or necessary for the treatment of the beneficiary's illness or injury, or billing more than one unit of GAUDX on a claim. Finally, because we are concerned about beneficiaries with acute onset conditions that require immediate medical intervention, and the potential loss of valuable time for medical intervention if the patient sees an audiologist first, we are limiting the direct access to audiology services to non-acute hearing conditions and conditions for which patients' experience disequilibrium symptomology. To help address these safety concerns about direct access to audiologists, we want to stress the importance that such hearing conditions with a rapid onset and balance conditions with disequilibrium symptoms are to be referred directly to the primary care physician, ENT or other physician or NPP treating the beneficiary.

5. Alternatives Related to Proposals for Medicare Part A and B Payment for Dental Services and Request for Information

As explained in this proposed rule, we believe there are instances where the medical services necessary for treating the individual's underlying medical condition and clinical status may require the performance of certain dental or oral health services. In these instances, we believe that the dental and oral health services are not in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth, and instead are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services such that the dental or oral health services are not subject to the statutory payment preclusion under section 1862(a)(12) of the Act. We also believe that there are circumstances where the dental or oral health services are in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth, and are not inextricably linked to the clinical success of an otherwise covered medical service such that Medicare payment for the dental or oral health services is precluded by section 1862(a)(12) of the Act. And we believe that there may circumstances where, because of the patient's underlying medical condition and clinical status or because the severity of the dental procedure, the patient requires hospitalization to receive services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth such that payment could be made under Medicare Part A for inpatient hospital services in connection with the dental or oral health services under the exception provided under section 1886(a)(12) of the Act.

In section II.L.2. of this proposed rule, we are: (1) proposing to clarify our interpretation of section 1862(a)(12) of the Act, and clarify and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposing and seeking comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; (3) requesting comments on other types of clinical scenarios where the dental services may be inextricably linked and substantially related and integral to the clinical success of other covered medical services; (4) requesting comments on the potential establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services; (5) requesting comment on other potentially impacted policies;, and (6) requesting comment on potential future payment models for dental and oral health care services.

We note that we are open to considering and finalizing payment under Medicare Parts A and B for dental services under additional circumstances to those for which payment is already made under our current policy or for which we are specifically proposing to make payment beginning in CY 2023. Specifically, we would consider finalizing Medicare Part A and Part B payment for dental services if there are other circumstances in which such dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth; but rather, are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. In that case, the dental services would not be subject to the Medicare payment exclusion provided under section 1862(a)(12) of the Act. We considered whether to propose Medicare payment for the performance of other services where a comprehensive dental or oral health exam, and potential treatment, might be considered a standard of care prior to the performance of an otherwise covered medical service, such as before certain treatment of head and neck cancers, such as radiation therapy with or without chemotherapy, before the initiation of medically necessary immunosuppressant therapy, such as those used during cancer treatments, prior to joint replacement surgery (such as total hip and knee arthroplasty surgery). However, we decided not to specifically propose payment in these circumstances because we believe more clinical data is necessary to determine whether the dental services would be inextricably linked to, and substantially related and integral to the clinical success of, these medically necessary services. We welcome public comments on all of these alternatives discussed, including whether Medicare payment should be specified for other types of services where the dental services may be so inextricably linked to the clinical success of an otherwise covered medical service that they are not in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting the teeth. We welcome public comments on these alternatives and others, which we may consider finalizing in the CY 2023 PFS final rule, or through future rulemaking after considering the comments received.

In section II.L.2.c.(ii) of this proposed rule, we seek comment on the potential establishment of a process to accept, review and consider additional clinical scenarios where payment may be permitted under Medicare Part A and Part B for certain additional dental services. We note that we considered establishing categorical clinical criteria and review process for submissions in order to consider whether these dental services are inextricably linked to an otherwise covered medical service, and therefore not subject to the Medicare payment exclusion provided under section 1862(a)(12) of the Act. However, we decided not to establish specific review criteria at this time because we believed a more open-ended clinical review process was preferable as we began to carefully consider payment policies for dental services in light of our longstanding interpretation of section 1862(a)(12) of the Act. We seek comment on alternative approaches to reviewing these submissions if we finalize the proposed process, such as outlining the specific types of medical literature needed to support the inclusion of services for Medicare FFS payment purposes, or legal and clinical analysis needed to consider whether the services do or do not fall within the statutory exclusion for dental services under section 1862(a)(12) of the Act based on our proposed interpretation within this proposed rule. We welcome public comments on these alternatives and others, which we may consider finalizing in the CY 2023 PFS final rule or future rulemaking after considering the comments received.

If we were to finalize a change in the CY 2023 PFS rulemaking to expand the types of dental services for which payment can be made under Medicare Parts A and B, we remain open to adjusting any finalized policy through future rulemaking, and conducting further impact analysis while also providing an opportunity for public comment on such analysis.

6. Alternatives Considered Related to Medicare Shared Savings Program

One purpose of the proposed prior savings adjustment is to mitigate the rebasing ratchet effect on an ACO's benchmark in order to improve the incentive for higher spending ACOs to reduce spending in advance of eventual rebasing and to encourage their renewal for successive agreement periods. It remains a possibility, however, that even with this provision, higher spending ACOs that are effective in reducing spending may eventually drop out of the Shared Savings Program absent the opportunity to participate in a one-sided model in the succeeding agreement period. While we project only 1 to 5 percent of new ACOs dropping out before the end of their first agreement period, the dropout rate could reach as high as 30 percent during the second agreement period. Signaling that risk will eventually be mandatory could prevent the formation of low-revenue ACOs for whom a sharing-only incentive has proven to be effective. We considered an alternative in which low revenue ACOs would be permitted to participate in a one-sided model for a second full agreement period and estimate it would further increase program savings by at least $1 billion because it would increase retention for the type of ACO that has favorably responded to a moderate upside-only incentive in the past. This additional savings would result from (1) about a 60 percent reduction in the projected dropout rate by the end of the second agreement period for new and re-entering ACOs and (2) an assumed incremental increase in the share of ACOs that would form as low revenue (a type that is assumed to be more effective at reducing spending). This alternative estimate is likely conservative, as the savings impact could be significantly greater if such signaling regarding the second agreement period were to prove to be a key factor motivating a significant increase in the overall number of ACOs that enter a first agreement period under the Shared Savings Program (instead of just the proportion that form as low revenue versus high revenue).

Commenters may support also adding guardrails for calculating shared savings by limiting the difference the ACPT may be allowed to show (in either direction) from actual national assignable trend. Setting a prospective symmetric threshold for correcting extreme projection error would automatically correct for bias in either direction and prevent the need for CMS to address pressure to correct projection error on an ad hoc basis. Public pressure to correct for projection error would be strongest in situations where actual growth eclipses the ACPT by a significant margin. If CMS were assumed to only update the ACPT in years where such pressures were magnified because a change would favor ACOs, this impact estimate would show $1.3 billion in additional spending over 10 years. This estimate presumes that CMS would limit deviation in ACPT from actual national trend to no more than 2 percent in years where the ACPT understates national trend. The cost of such policy to asymmetrically correct for unfavorable projection error would grow if the threshold for making such adjustments were assumed to move lower than 2 percent.

7. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran separate proposed policies RIA models based on the actual mean for the CY 2019 performance period/2021 MIPS payment year and the CY 2020 performance period/2022 MIPS payment year with a performance threshold of 86 and 89, respectively which are potential values that may be used for the performance threshold for CY 2023 performance period/2025 MIPS payment year. The models have the same mean and median final score as our proposed policies RIA model since the performance threshold does not change the final score. In the iteration with a performance threshold of 86, 82.3 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 89 points, 89.1 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

We report the findings for the baseline RIA model which describes the impact for the CY 2023 MIPS performance period/2025 MIPS payment year if this proposed regulation did not exist. The baseline RIA model has a mean final score of 73.63 and median final score of 77.48. We estimate that $1 billion would be redistributed through budget neutrality. There would be a maximum payment adjustment of 6.8 percent after considering the MIPS payment adjustment. In addition, 39.4 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

G. Impact on Beneficiaries

1. Shared Savings Program Provisions

As noted previously, a number of changes in this proposed rule collectively aim to increase participation in a more sustainable way for ACOs serving medically complex, high cost beneficiaries. The proposed policies are designed to reverse recent trends where growth has plateaued in the Shared Savings Program, higher spending populations are increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to ACOs appears inequitable as evidenced by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO than their Non-Hispanic White counterparts, and to encourage growth of ACOs in underserved communities.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In addition, ACOs have consistently demonstrated their ability to improve quality with 64 percent of ACOs participating during both 2019 and 2020 receiving Quality Improvement Reward points with the majority of ACOs showing the greatest improvement in the Preventive Health domain.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management, and would stave off the risk apparent in the current trajectory of the Shared Savings Program where ACO participants and ACO providers/suppliers may feel pressure to avoid engaging with beneficiaries in high needs communities in order to avoid assignment of high cost beneficiaries to their ACO and to improve their performance relative to a regional expenditures. In combination with proposed new participation options that are expected attract a mix of new participants, targeted proposals such as using an offset factor to reduce the negative regional adjustment for ACOs serving high risk and high dual populations, aim to increase the reach of ACO care coordination to more beneficiaries with high needs.

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and

subgroup proposals, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate this will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's rule will be the number of reviewers of last year's rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the rule. For these reasons we thought that the number of commenters will be a fair estimate of the number of reviewers of last year's rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it will take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $921.76 (8.0 hours × $115.22). Therefore, we estimated that the total cost of reviewing this regulation is $32,657,957 ($931.35 × 35,430 reviewers on last year's proposed rule).

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 150 through 152 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2021 to CY 2022 based on the FY 2022 President's Budget baseline.

TABLE 150: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2023 Annualized Monetized Transfers	Estimated increase in expenditures of -$2.2 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 151: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2023 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.6 billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 152: Accounting Statement for Proposals for Medicare Shared Savings Program (CYs 2023-2034)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-1,139 million	-458 million	-1,744 million	Table 142
Annualized monetized: Discount rate: 3%	-1,197 million	-484 million	-1,876 million	

Notes: Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure,

Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 21, 2022.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health insurance, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.2463 is amended by revising paragraph (b)(3) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(b) * * *

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning 152 days after the end of the COVID–19 public health emergency, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

■ 3. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit

a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning 152 days after the end of the COVID–19 public health emergency, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 5. Amend § 410.10 by revising paragraphs (l) and (p) to read as follows—

§ 410.10 Medical and other health services: Included services.

* * * * *

(l) Pneumococcal, influenza, and COVID–19 vaccines and their administration.

* * * * *

(p) Hepatitis B vaccine and its administration, as defined in § 410.63(a) of this subchapter.

* * * * *

■ 6. Amend § 410.26 by revising paragraph (b)(5) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 7. Amend § 410.32 by adding paragraph (a)(4), as follows:

§ 410.3 2 Diagnostic x-ray tests, diagnostic laboratory test, and other diagnostic tests: Conditions.

(a) * * *

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a code CMS designates for this purpose.

* * * * *

■ 8. Amend § 410.37—

■ a. In paragraph (c)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'';

■ b. In paragraph (c)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'';

■ c. In paragraph (e)(1), by removing the phrase ''under age 50'' and adding in its place the phrase ''under age 45'';

■ d. In paragraph (e)(2), by removing the phrase ''individual 50 years of age'' and adding in its place the phrase ''individual 45 years of age'';

■ e. In paragraph (i)(1), by removing the phrase ''individual age 50'' and adding in its place the phrase ''individual age 45''; and

■ f. By adding paragraph (k).

The addition reads as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(k) *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

■ 9. Amend § 410.40 by revising paragraph (e)(2)(ii) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(e) * * *

(2) * * *

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

* * * * *

■ 10. Amend § 410.57 by—

■ a. Revising the section heading and paragraph (a); and

■ b. Adding paragraph (d).

The revisions and addition read as follows:

§ 410.57 Preventive vaccines.

(a) Medicare Part B pays for the pneumococcal vaccine and its administration.

* * * * *

(d) Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).

§ 410.63 [Amended]

■ 11. Amend § 410.63 in the introductory text by removing the phrase ''vaccines (see § 405.310 of this chapter)'' and adding in its place the phrase ''vaccines (see § 411.15 of this chapter)''.

■ 12. Amend § 410.67 by—
■ a. Revising paragraphs (b)(6) and (d)(2)(i)(B)(*2*);
■ b. Adding paragraph (d)(2)(iv); and
■ c. Revising paragraph (d)(4)(ii).

The revisions and addition read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

(6) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title. Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(B) * * *

(*2*) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021. For CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021 and updated by the PPI for Pharmaceuticals for Human Use (Prescription).

* * * * *

(iv) *Increased level of psychotherapy.* For CY 2023 and subsequent years, the payment for the non-drug component of the bundled payment for an episode of care under paragraph (d)(2) of this section is adjusted to reflect the CY 2019 Medicare physician fee schedule non-facility rate for psychotherapy, 45 minutes with patient.

* * * * *

(4) * * *

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

* * * * *

§ 410.78 [Amended]

■ 13. Amend § 410.78 in paragraph (b)(3)(xiv), by removing the phrase ''the first day'' and adding in its place the phrase ''the day that is the 152nd day''.

■ 14. Amend § 410.152—
■ a. By revising paragraph (h);
■ b. In paragraph (l)(1), by removing the phrase ''(as specified in paragraph (h) of this section)''.

The revision reads as follows:

§ 410.152 Amounts of payment.

* * * * *

(h) *Amount of payment: Preventive vaccine administration.* For the administration of the preventive vaccines described in paragraph (l)(1) of this section, as furnished by providers described in §§ 409.100 and 410.150 of this subchapter, Medicare Part B pays the following amounts, except as otherwise provided under this subchapter:

(1) Effective January 1, 2022, for administration of an influenza, hepatitis B or pneumococcal vaccine, $30 per dose.

(2) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(3) For services furnished on or after January 1 of the year following the year in which the Secretary ends the Emergency Use Authorization for drugs and biologicals issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1).

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) through (3) of this section is adjusted to reflect geographic cost variations:

(i) For services furnished before January 1, 2023, using the Geographic Practice Cost Indices (GPCIs) established for the year, as described in section 1848(e)(1) of the Act and §§ 414.2 and 414.26 of this subchapter.

(ii) For services furnished on or after January 1, 2023, using the Geographic Adjustment Factor (GAF) established for the year as described in section 1848(e)(2) of the Act and §§ 414.2 and 414.26 of this subchapter.

(5) The payment amount for administration of a preventive vaccine described in paragraphs (h)(1) through (3) of this section is updated annually using the percentage change in the Medicare Economic Index (MEI) as described in section 1842(i)(3) of the Act and § 405.504(d) of this subchapter.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 15. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 16. Section 411.15 is amended by revising paragraph (i) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) *Dental services.*—(1) *Basic rule. Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth,

(2) *Exception. Except for* inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(i) The individual's underlying medical condition and clinical status; or

(ii) The severity of the dental procedures.[1]

(3) *Inapplicability.* (i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Part A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the organ transplant, cardiac valve replacement, or valvuloplasty procedure.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

[1] Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient's underlying medical condition and clinical status.

(C) The wiring or immobilization of teeth in connection with the reduction of a jaw fracture.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(E) Dental splints only when used in conjunction with covered treatment of a covered medical condition.

(ii) Ancillary services and other supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the service is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 17. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 18. Amend § 414.502 by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2023 through March 31, 2023.

* * * * *

§ 414.504 [Amended]

■ 19. Amend § 414.504 in paragraph (a)(1) by removing the reference ''January 1, 2022'' and adding in its place the reference ''January 1, 2023''.

■ 20. Amend § 414.507 by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(5);

■ b. Adding paragraph (d)(8); and

■ c. Removing paragraph (f).

■ d. Redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2025, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(5) 2022—0.0 percent of the payment rate established in 2021.

* * * * *

(8) 2025—15 percent of the payment rate established in 2024.

* * * * *

■ 21. Section § 414.523 is added to subpart G to read as follows:

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) *Specimen collection fee and travel allowance.* In addition to the payment amounts provided under this subpart for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee, as set forth in paragraph (a)(1) of this section, and a travel allowance, as set forth in paragraph (a)(2) of this section.

(1) *Payment for specimen collection.* Except as provided in paragraph (a)(1)(iv) of this section, CMS pays $3 for all specimens collected in one patient encounter, where the specimen(s) is:

(i) Used to perform a CDLT paid under this subpart G;

(ii) Collected by a trained technician from a Medicare beneficiary who is—

(A) Homebound as described in 42 CFR 424.22(a)(1)(ii).

(B) A non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen;

(iii) Of the following type—

(A) Blood specimen collected through venipuncture.

(B) A urine sample collected by catheterization.

(iv) Beginning April 1, 2014, for a specimen collected from a Medicare beneficiary in a skilled nursing facility or on behalf of a home health agency, the specimen collection fee otherwise paid under paragraph (a)(1) of this section is increased by $2.

(2) *Payment for travel allowance*—(i) *General requirement.* CMS pays a travel allowance, as calculated under paragraph (a)(2)(iii) of this section, where the specimen is one for which a specimen collection fee is paid under paragraph (a)(1) of this section.

(ii) *Travel allowance basis.* CMS pays a travel allowance on the following bases:

(A) *Flat-rate travel allowance.* The flat-rate travel allowance applies when the trained technician travels 20 eligible miles or less (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(B) *Per-mile travel allowance.* The per-mile travel allowance applies when:

(*1*) The trained technician travels more than 20 eligible miles (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(*2*) The trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

(iii) *Travel allowance amount*—(A) *Eligible miles.* Eligible miles begin at the laboratory and end at the laboratory where the trained technician returns the specimen(s) for testing. Eligible miles do not include miles traveled for any purpose unrelated to specimen collection as specified in paragraph (a)(1) of this section, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

(B) *Travel allowance mileage rate.* The travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the United States Bureau of Labor Statistics, divided by 40 to represent an average miles-per-hour driving speed.

(C) *Travel allowance amount calculation.* (*1*) For the flat-rate travel allowance basis specified in paragraph (a)(2)(ii)(A) of this section, the travel allowance amount is the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section multiplied by ten, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(*2*) For the per-mile travel allowance basis specified in paragraph (a)(2)(ii)(B) of this section, the travel allowance amount is the number of eligible miles multiplied by the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(b) [Reserved]

§ 414.626 [Amended]

■ 22. Amend § 414.626—

■ a. In paragraph (d)(1) introductory text, by removing the phrase ''must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS'' and adding in its place the phrase ''must submit a request to CMS, in the form and manner specified by CMS,''; and

■ b. In paragraph (e)(2) introductory text, by removing the phrase ''by submitting all of the following information:'' and adding in its place the phrase ''by submitting a request to CMS, in the form and manner specified by CMS, that includes all of the following information:''.

§ 414.707 [Amended]

■ 23. Amend § 414.707 in paragraph (a)(2)(iii), by removing the phrase ''(as determined by the Secretary)'' and adding in its place the phrase ''(as defined in § 410.63(a) of this subchapter).''

■ 24. Amend § 414.902 by adding the definition of ''Refundable single-dose container or single-use package drug'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Refundable single-dose container or single-use package drug means a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information. The term ''refundable single-dose container or single-use package drug'' excludes—

(1) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(2) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(3) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

* * * * *

§ 414.904 [Amended]

■ 25. Amend 414.904 in paragraph (e)(1), by removing the phrase ''(as determined by the Secretary)'' and adding in its place the phrase ''(as defined in § 410.63(a) of this subchapter).''

■ 26. Section § 414.940 is added to subpart K to read as follows:

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Reports.* Reports are sent once annually in the following manner:

(i) For 2023, the report is sent no later than October 1 of that year and includes only the first calendar quarter of 2023.

(ii) Beginning in 2024 and for all subsequent years, the report is sent no later than October 1 of the given year and includes the second, third, and fourth calendar quarters of the prior year and the first calendar quarter of the current year.

(iii) Beginning in 2024 and for all subsequent years, the report includes new information (as described in paragraph (a)(1)(i) of this section) for the second, third, and fourth calendar quarter of the year that is 2 years prior and the first calendar quarter of the prior year that was not reflected in the previous year's report.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts that the manufacturer is liable for pursuant to this paragraph are paid in 12-month intervals no later than December 31 of the year in which the report was sent to the manufacturer, in a manner specified by CMS.

(2) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(1) The product of:

(i) The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

(ii) The amount of payment determined for such drug or biological under this section for such quarter.

(2) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the quarter.

(3) For purposes of paragraph (c)(1)(ii) of this section, the term ''applicable percentage'' means 10 percent.

(d) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s)

that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(e) *Enforcement.* (1) *Manufacturer audits.* Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this subsection shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

■ 27. Section § 414.1305 is amended by—

■ a. Adding the definition of ''Facility-based group'';

■ b. Revising the definitions of ''Facility-based MIPS eligible clinician'', ''High priority measure'', ''Multispecialty group'', ''Single specialty group'', and ''Third party intermediary'' to read as follows:

§ 414.1305 Definitions.

* * * * *

Facility-based group means a group that CMS determines meets the criteria specified in § 414.1380(e)(2)(ii).

Facility-based MIPS eligible clinician means an individual MIPS eligible clinician who CMS determines meets the criteria specified in § 414.1380(e)(2)(i).

* * * * *

High priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure.

* * * * *

Multispecialty group means a group as defined at § 414.1305 that consists of two or more specialty types as determined by CMS using Medicare Part B claims.

* * * * *

Single specialty group means a group as defined at § 414.1305 that consists of one specialty type as determined by CMS using Medicare Part B claims.

* * * * *

Third party intermediary means an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

* * * * *

■ 28. Amend § 414.1318 by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraphs (a)(3) and (4); and

■ c. Revising paragraphs (b) and (c)(2).

The revisions and addition read as follows:

§ 414.1318 Subgroups.

(a) * * *

(1) *General.* Except as provided under paragraph (a)(2) of this section and subject to paragraph (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310.

* * * * *

(3) *Single subgroup per eligible clinician.* An individual eligible clinician (as represented by a TIN–NPI combination) may register for no more than one subgroup within a group's TIN.

(4) *Subgroup determination period.* CMS will apply the low-volume threshold criteria for a subgroup as described under paragraph (a)(1) of this section using information from the initial 12-month segment of the applicable MIPS determination period.

(b) *Final score.* Except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance.

(1) CMS will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period.

(2) [Reserved]

(c) * * *

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with § 414.1365. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b).

■ 29. Amend § 414.1340 by adding paragraphs (a)(4) and (b)(4) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(4) At least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026 and 2027.

* * * * *

(b) * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026 and 2027.

* * * * *

■ 30. Amend § 414.1365 by—

■ a. Adding paragraphs (b)(2)(iii);

■ b. Revising paragraph (d)(3)(i)(A)(*1*);

■ c. Adding paragraph (d)(3)(i)(B)(*1*);

■ d. Reserving paragraph (d)(3)(i)(B)(*2*);

■ e. Adding paragraph (d)(3)(ii)(A); and

■ f. Reserving paragraph (d)(3)(ii)(B).

The additions and revisions read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(iii) TINs must provide a description of each subgroup that is registered.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) * * *

(*1*) A subgroup is scored on each selected population health measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

* * * * *

(B) * * *

(*1*) A subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points.

(*2*) [Reserved]

(ii) * * *

(A) A subgroup is scored on each cost measure included in the MVP that it

selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v).

(B) [Reserved]

* * * * *

■ 31. Amend § 414.1380 by—

■ a. Adding paragraph (b)(1)(ii)(D); and

■ b. Revising paragraphs (b)(2)(iv)(E), (b)(4)(ii)(B) and (C), (c)(2)(i)(A)(*4*)(*i*) and (*iii*), (c)(3) introductory text, (e)(2) introductory text, (e)(2)(ii), (e)(4), (e)(5)(i) and (ii), (e)(6)(iv) and (v), and (e)(6)(vi)(A) and (B).

The addition and revisions read as follow:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(D) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

* * * * *

(2) * * *

(iv) * * *

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. The maximum cost improvement score beginning with the 2024 MIPS payment year is 1 percentage point.

* * * * *

(4) * * *

(ii) * * *

(B) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each required measure is worth 10, 20, or 40 points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each required measure is worth 10, 15, 25 or 30 points, as specified by CMS.

(C) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth five or ten bonus points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five bonus points, as specified by CMS.

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) * * *

(*i*) For the 2021 through 2025 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(*iii*) For the 2024 through 2025 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (iv) of this section. For the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section. Beginning with the CY 2023 MIPS performance period/CY 2025 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, or is a facility-based MIPS eligible clinician, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section.

* * * * *

(e) * * *

(2) *Eligibility for facility-based measurement.* A MIPS eligible clinician is eligible for facility-based measurement for a MIPS payment year if CMS determines the MIPS eligible clinician to be facility-based as an individual clinician or as part of a group, or beginning with the 2023 performance period/2025 MIPS payment year, a virtual group, as follows:

* * * * *

(ii) *Facility-based MIPS eligible group determination.* A facility-based MIPS eligible group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

* * * * *

(4) *Data submission for facility-based measurement.* There are no data submission requirements for a MIPS eligible individual clinician to be scored under facility-based measurement. A MIPS eligible group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be scored as a facility-based MIPS eligible group.

(5) * * *

(i) A facility-based MIPS eligible clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based MIPS eligible group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) * * *

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not

eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category.

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or MIPS eligible group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

* * * * *

(vi) * * *

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a MIPS eligible clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a MIPS eligible clinician or group receives a higher MIPS final score through another MIPS submission.

■ 32. Amend § 414.1400 by—

■ a. Revising paragraphs (b)(4)(i)(B), (b)(4)(iii)(A)(*3*), and (e)(1)(i)(B);

■ b. Adding paragraphs (e)(1)(i)(E);

■ c. Revising paragraph (e)(2) introductory text and (e)(3);

■ d. Adding paragraph (e)(5); and

■ e. Revising paragraph (f)(1).

The revisions and additions read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, NQF number (if NQF—endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

* * * * *

(iii) * * *

(A) * * *

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.

* * * * *

(e) * * *

(1) * * *

(i) * * *

(B) The impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

* * * * *

(E) The communication plan for communicating the impact to the parties identified in paragraph (e)(1)(i)(B) of this section.

(2) CMS may immediately or with advance notice terminate a third party intermediary for one or more of the following reasons:

* * * * *

(3) A data submission that contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

* * * * *

(5) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(f) * * *

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

* * * * *

■ 33. Amend § 414.1405 by revising paragraph (b)(9) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) Pursuant to the methodology established at paragraph (g) of this section:

(i) The performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) The performance threshold for the 2025 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

■ 34. Amend § 414.1415 by—

■ a. Revising paragraphs (b)(3),

■ b. Adding paragraph (b)(4); and

■ c. Revising paragraphs (c)(3)(i)(A) and (c)(7).

The revisions and addition read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(b) * * *

(3) The quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

(4) A single quality measure that meets the criteria under both paragraphs (b)(2) and (3) of this section may be used to satisfy the requirements of paragraph (b)(1) of this section.

(c) * * *

(3) * * *

(i) * * *

(A) For QP Performance Periods beginning in 2023, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(7) *Medical Home Model 50 eligible clinician limit.* Beginning in the 2023 QP Performance Period, notwithstanding paragraphs (c)(2) and (4) of this section, if an APM Entity participating in a Medical Home Model is comprised of more than 50 eligible clinicians, as determined by that APM Entity's Participation List on any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period), the requirements of paragraphs (c)(1) and (3) of this section apply.

■ 35. Amend § 414.1420 by—
■ a. Revising paragraph (c)(3)(ii);
■ b. Adding paragraph (c)(4); and
■ c. Revising paragraphs (d)(3)(i) and (d)(8).

The revisions and addition read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(c) * * *

(3) * * *

(ii) For QP Performance Periods on or after January 1, 2020, use at least one measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

(4) A single quality measure that meets the criteria under both paragraphs (c)(2) and (3) of this section may be used to satisfy the requirements of paragraph (c)(1) of this section.

(d) * * *

(3) * * *

(i) For QP Performance Periods beginning in 2023, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

* * * * *

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Beginning with the 2023 QP Performance Period, notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is comprised of 50 or more eligible clinicians is comprised of more than 50 eligible clinicians, as determined by the information submitted for any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period) as specified in § 414.1440(e), the requirements of paragraphs (d)(1) and (3) of this section apply.

■ 36. Amend § 414.1430 by—
■ a. Revising paragraphs (a)(2)(iii);
■ b. Removing the second paragraph (a)(3)(ii);
■ c. Adding paragraphs (a)(3)(iii) and (iv);
■ d. Revising paragraph (a)(4)(iii);
■ e. Adding paragraph (a)(4)(iv); and
■ f. Revising paragraphs (b)(3)(i)(A) and (B), and (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(2) * * *

(iii) 2023 and 2024: 40 percent.

* * * * *

(3) * * *

(iii) 2023 and 2024: 35 percent.

(iv) 2025 and later: 50 percent.

(4) * * *

(iii) 2023 and 2024: 25 percent.

(iv) 2025 and later: 35 percent.

(b) * * *

(3) * * *

(i) * * *

(A) 2021 through 2024: 35 percent.

(B) 2025 and later: 50 percent.

* * * * *

(4) * * *

(i) * * *

(A) 2021 through 2024: 25 percent.

(B) 2025 and later: 35 percent.

* * * * *

■ 37. Amend § 414.1440 by revising paragraph (e)(2) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

* * * * *

(e) * * *

(2) To request a QP determination under the All-Payer Combination Option, for each payment arrangement submitted as set forth in paragraph (e)(1) of this section, the APM Entity or eligible clinician must include:

(i) The amount of revenue for services furnished through the payment arrangement, the total revenue received from all payers except those excluded as provided in paragraph (a)(2) of this section, the number of patients furnished any service through the arrangement, and the total number of patients furnished any services, except those excluded as provided in paragraph (a)(2) of this section; and

(ii) In the case of an APM Entity or eligible clinician requesting a QP determination under either a Medicaid Medical Home Model or Aligned Other Payer Medical Home Model pursuant to the criteria in § 414.1420, information specified by CMS for purposes of compliance with the 50 eligible clinician limit specified at § 414.1420(d)(8).

* * * * *

§ 414.1450 [Amended]

■ 38. Amend § 414.1450(c)(8) by removing the reference ''November 1'' and adding in its place the reference ''September 1''.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 39. The authority for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 415.140 [Amended]

■ 40. Amend § 415.140 by redesignating this section from subpart D to subpart C in numerical order.

■ 41. Amend § 415.140(a) in the definition of ''Substantive portion'' by removing the reference ''2022'' and adding in its place the reference ''2022 and 2023''.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 42. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 43. Amend § 423.160 by revising paragraphs (a)(5)(ii) and (iii) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) * * *

(ii) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.

(iii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 44. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 45. Amend § 424.57 by adding paragraph (b)(6) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(b) * * *

(6) The supplier is in compliance with all conditions of payment in paragraph (b) of this section, as well as with paragraph (c)(1)(ii)(A) of this section, at the time the item or service is furnished.

* * * * *

■ 46. Amend § 424.502 by adding the definitions of ''Director'', ''Managing organization'' and ''Officer'' in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Director means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.

* * * * *

Managing organization means an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

* * * * *

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

* * * * *

■ 47. Amend § 424.518 by—
■ a. Revising the introductory text;
■ b. Removing paragraph (a)(1)(xviii);
■ c. Adding paragraphs (b)(1)(xiv);
■ d. Revising paragraph (c)(1) introductory text; and
■ e. Adding paragraphs (c)(1)(v) and (vi), and (c)(4).

The revision and additions read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, revalidation applications, change of ownership applications pursuant to 42 CFR 489.18, applications to add a new practice location, and applications to report any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42, based on a CMS assessment of risk and assignment to a level of ''limited,'' ''moderate,'' or ''high.''

* * * * *

(b) * * *

(1) * * *

(xiv) Revalidating skilled nursing facilities (SNFs)

* * * * *

(c) * * *

(1) *High categorical risk: Provider and supplier categories.* CMS has designated the following provider and supplier types as ''high'' categorical risk:

* * * * *

(v) Prospective (newly enrolling) skilled nursing facilities (SNFs).

(vi) Enrolled OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, and SNFs that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

* * * * *

(4) Any screening level adjustment under paragraph (c)(3) of this section also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under paragraph (c)(3) of this section was originally raised.

* * * * *

■ 48. Amend § 424.530 by—
■ a. Revising paragraph (a)(2) and paragraph (a)(3) introductory text;
■ b. Adding paragraph (a)(3)(iii); and
■ c. Revising paragraph (c).

The revisions and addition read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(2)(i) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.* The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

* * * * *

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, managing organization, officer, director, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

* * * * *

■ 49. Amend § 424.535 by—
■ a. Revising paragraphs (a)(2) and (a)(3)(i);
■ b. Adding paragraph (a)(3)(iv); and
■ c. Revising paragraphs (a)(12)(ii) and (e).

The revisions and addition read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(2)(i) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical

director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) * * *

(i) The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(iv) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

* * * * *

(12) * * *

(ii) Medicare may not revoke unless and until a provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal.

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 50. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§ 425.20 [Amended]

■ 51. Amend § 425.20 by—

■ a. In paragraph (2) of the definition of ''Experienced with performance-based risk Medicare ACO initiatives'' by removing the phrase ''prior to the agreement start date'';

■ b. In paragraph (2) of the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives'' by removing the phrase ''prior to the agreement start date''

■ c. Revising paragraph (1)(i) in the definition of ''Performance-based risk Medicare ACO initiative'';.

■ d. Redesignating paragraphs (1)(ii) and (1)(iii) as paragraphs (1)(iii) and (1)(iv), respectively; in the definition of ''Performance-based risk Medicare ACO initiative'' by and

■ e. Adding paragraph (1)(ii) in the definition of ''Performance-based risk Medicare ACO initiative''.

§ 425.20 Definitions.

* * * * *

Performance-based risk Medicare ACO initiative

* * * * *

(1) * * *

(i) For performance years beginning prior to January 1, 2023, BASIC track (Levels A through E).

(ii) For performance years beginning January 1, 2023 and in subsequent years, BASIC track (Levels C through E).

* * * * *

■ 52. Amend § 425.100 by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraph (d).

The revision and addition read as follows:

§ 425.100 General.

* * * * *

(b) * * *

(1) The ACO meets or exceeds the applicable minimum savings rate established under §§ 425.604, 425.605 (except as provided under § 425.605(h)), 425.606, 425.609, or 425.610.

* * * * *

(d) An ACO is eligible to receive advance investment payments if it meets the criteria under § 425.630(b).

§ 425.204 [Amended]

■ 53. Amend § 425.204(g) by removing the references ''§ 425.601, § 425.602, or § 425.603'' and adding in its place the references ''§§ 425.601, 425.602, 425.603, or 425.652''.

§ 425.224 [Amended]

■ 54. Amend § 425.224(a)(4) by removing the phrase '', or a one-sided model of the BASIC track's glide path (Level A or Level B),''.

■ 55. Amend § 425.302 by adding paragraph (a)(3)(iv) to read as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iv) That the ACO has moved all advance investment payments received during that performance year into a designated advance investment payments account established under § 425.630(e) and the advance investment payments have been dispersed only for allowable uses.

* * * * *

■ 56. Amend § 425.308 by adding paragraph (b)(8) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(8) Information, updated annually about the ACO's use of advance investment payments under § 425.630, for each performance year, including the following:

(i) The ACO's spend plan.

(ii) The total amount of any advance investment payments received from CMS.

(iii) An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under § 425.630(d), and such other information as may be specified by CMS.

* * * * *

■ 57. Section 425.310 is revised to read as follows:

§ 425.310 Marketing requirements.

(a) R*equirements.* Marketing materials and activities must:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304 regarding beneficiary incentives.

(4) Not be materially inaccurate or misleading.

(b) *Monitoring.* (1) CMS may request the submission of marketing materials

and activities at any time. If CMS determines that the marketing materials and activities do not comply with the requirements of paragraph (a) of this section, CMS will issue written notice of disapproval to the ACO.

(2) The ACO shall discontinue, and require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue, use of any marketing materials or activities disapproved by CMS.

(c) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

■ 58. Amend § 425.312 by revising paragraph (a)(2) to read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) Notification of the information specified in paragraph (a)(1) of this section must be carried out through the following methods:

(i) By an ACO participant posting signs in all of its facilities.

(ii) By an ACO participant making standardized written notices available upon request in all settings in which beneficiaries receive primary care services.

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each fee-for-service beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all fee-for-service beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

(iv) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished during the performance year for which the beneficiary is prospectively assigned to the ACO.

(v) Following the provision of the standardized written notice to a beneficiary, as specified in paragraphs (a)(2)(iii) and (iv) of this section, the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary.

(A) The follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided.

(B) The ACO must retain a record of all beneficiaries receiving the follow-up communication, and the form and manner in which the communication was made available to the beneficiary. The ACO must make these records available to CMS upon request.

* * * * *

■ 59. Amend § 425.316 by adding paragraph (e) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(e) *Monitoring ACO eligibility for advance investment payments.* (1) CMS monitors an ACO that receives advance investment payments pursuant to § 425.630 for changes in its ACO participants that may cause the ACO to no longer meet the standards specified in § 425.630(b)(3) and (4).

(2) If CMS determines that an ACO receiving advance investment payments is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, CMS—

(i) Will cease payment of advance investment payments, starting the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

(ii) May take compliance action as specified in §§ 425.216 and 425.218.

(3) If an ACO remains an ACO experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action under this section, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

■ 60. Amend § 425.400 by—

■ a. Revising paragraph (c)(1)(vi) introductory text; and

■ b. Adding paragraph (c)(1)(vii).

The addition and revision read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(vi) For the performance year starting on January 1, 2022 as follows:

* * * * *

(vii) For the performance year starting on January 1, 2023, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vii)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*9*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*10*) 99439 (code for non-complex chronic care management).

(*11*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*12*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*13*) 99495 and 99496 (codes for transitional care management services).

(*14*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2212, GXXX2, and GXXX3 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(*14*) GYYY1 and GYYY2 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 61. Amend § 425.402 by adding paragraph (f) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(f) For performance year 2023 and subsequent performance years, CMS employs the following process to identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of the beneficiary assignment methodology under this section.

(1) Prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status.

(2) CMS uses the CCNs identified in paragraph (f)(1) of this section in determining assignment for the performance year.

(3) CMS accounts for changes in CCN enrollment status during the performance year as follows:

(i) If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS will consider services furnished by that CCN in determining beneficiary assignment to the ACO for the applicable performance year for ACOs under preliminary prospective assignment with retrospective reconciliation.

(ii) Services furnished by a CCN with a deactivated enrollment status that is enrolled under an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.

(iii) If a CCN enrolled under the TIN of an ACO participant at the start of the performance year enrolls under a different TIN during a performance year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

■ 62. Amend § 425.512—

■ a. In paragraph (a)(4)(i)(A), by removing the phrase ''quality performance score'' and adding in its place the phrase ''health equity adjusted quality performance score'';

■ b. By redesignating paragraph (a)(4)(ii) as paragraph (a)(4)(iii);

■ c. By adding new paragraph (a)(4)(ii);

■ d. Revising newly redesignated paragraph (a)(4)(iii);

■ e. By revising paragraph (a)(5)(i);

■ f. By redesignating paragraph (a)(5)(ii) as paragraph (a)(5)(iii);

■ g. By adding new paragraph (a)(5)(ii);

■ h. By revising newly redesignated paragraph (a)(5)(iii);

■ i. By adding paragraph (a)(6);

■ j. By redesignating paragraph (b) as paragraph (c);

■ k. By adding new paragraph (b);

■ l. In newly redesignated paragraph (c)(2) introductory text, by removing the reference ''paragraph (b)(1) of this section'' and adding in its place the reference ''paragraph (c)(1) of this section''; and

■ m. By revising newly redesignated paragraph (c)(3).

The revisions and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(4) * * *

(ii) For performance year 2023, CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraphs (a)(2) or (a)(4)(i) of this section, but reports quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.

(iii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

* * * * *

(5) * * *

(i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and the following:

(A) For performance year 2024—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

(B) For performance year 2025 and subsequent years—Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraphs (a)(2) or (a)(5)(i) of this section, but reports quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.

(iii) An ACO will not meet the quality performance standard or the alternative quality performance standard if:

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP.

(B) For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP.

(6) For performance years 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b).

(b) *Calculation of ACO's health equity adjusted quality performance score for* performance year 2023 and subsequent performance years.

(1) For an ACO that reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(2) of this section. The sum of these values may not exceed 100 percent.

(2) CMS calculates the ACO's health equity adjustment bonus points as follows:

(i) For each measure in the APP measure set, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(2)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates an underserved multiplier for the ACO.

(A) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the higher value of either the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index national percentile rank of at least 85 or the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid.

(B) If the proportion determined in accordance with paragraph (b)(2)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for health equity adjustment bonus points.

(v) Except as specified in paragraph (b)(2)(iv)(B) of this section, CMS calculates the ACO's health equity adjustment bonus points as the product of the measure performance scaler determined under paragraph (b)(2)(iii) of this section and the underserved multiplier determined under paragraph (b)(2)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's health equity adjustment bonus points is set equal to 10.

(3) The ACO's health equity adjusted quality performance score, determined in accordance with paragraphs (b)(1) and (b)(2) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), and (a)(5)(i)(B) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraphs (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i) and (a)(5)(i) of this section or the alternative quality performance standard established in paragraphs (a)(4)(ii) of this section.

(iv) In determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) and (iii) of this section.

(c) * * *

(3) If the ACO reports quality data via the APP and meets data completeness and case minimum requirements:

(i) For performance years 2021 and 2022, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 and subsequent performance years, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

■ 63. Amend § 425.600—

■ a. By revising paragraph (a)(4)(i)(B) introductory heading;

■ b. In paragraph (a)(4)(i)(B)(*2*)(*ii*), revise the last sentence.

■ c. In paragraph (a)(4)(i)(B)(*2*)(*iv*), by removing the phrase ''For performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022'' and adding in its place the phrase ''Except as provided in paragraph (a)(4)(i)(B)(*2*)(*vi*) of this section, for performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022'';

■ d. By adding paragraphs (a)(4)(i)(B)(*2*)(*vi*) and (*vii*), and (a)(4)(i)(C);

■ e. In paragraph (a)(4)(ii), by removing the reference ''paragraph (d) of this section'' and adding in its place the references ''paragraph (d) or paragraph (g)(2) of this section, as applicable'';

■ f. In paragraph (d) introductory text, by removing the phrase ''beginning on July 1, 2019, and in subsequent years'' and adding in its place the phrase ''beginning on or after July 1, 2019, and before January 1, 2024'';

■ g. By revising paragraph (e) introductory text;

■ h. In paragraph (f)(4)(ii), by removing the reference ''§ 425.601(f)'' and adding in its place the references ''§§ 425.601(f), and 425.656(d)'';
■ i. In paragraph (f)(4)(iii), by removing the reference ''§ 425.601(e)'' and adding in its place the references ''§§ 425.601(e), and 425.652(c)(2)''; and
■ j. By adding paragraphs (g) and (h).

The revisions and additions read as follows:

§ 425.600 Selection of risk model.

(a) * * *

(4) * * *

(i) * * *

(B) *Glide path progression for agreement periods beginning on or after July 1, 2019 and before January 1, 2024.*

* * * * *

(*2*) * * *

(*ii*) * * * In the case of an ACO that elects to remain in Level B for an additional performance year pursuant to the second sentence of paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section, and except as provided in paragraph (a)(4)(i)(B)(2)(*vi)* of this section, the ACO is automatically advanced to Level E under paragraph (a)(4)(i)(A)(*5*) of this section at the start of performance year 4 (or performance year 5 in the case of ACOs entering an agreement period beginning on July 1, 2019).

* * * * *

(*vi*) For performance year 2023, an ACO in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2022, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2023, the ACO is automatically advanced to the next level of the BASIC track's glide path to which the ACO would have automatically advanced absent any election to maintain its participation level for performance year 2022 under paragraph (a)(4)(i)(B)(*2*)(*iv*) of this section and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*vii*) For performance year 2024, an ACO with an agreement period beginning January 1, 2023 in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2023, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2024, the ACO is automatically advanced to the next level of the BASIC track's glide path, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

* * * * *

(C) *Glide path progression for agreement periods beginning on or after January 1, 2024.*

(*1*) *Level of glide path entry.* An ACO eligible to enter the BASIC track's glide path as determined under paragraph (g)(1) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*2*) *Automatic advancement.* An ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except as follows:

(*i*) The ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*ii*) The ACO elects to maintain its level of participation as provided in paragraph (a)(4)(i)(C)(*3*) of this section.

(*iii*) The ACO is automatically advanced to Level E pursuant to paragraph (h)(2)(i) of this section.

(*3*) *Election to remain under a one-sided model.* An eligible ACO that enters the BASIC track's glide path at Level A under paragraph (a)(4)(i)(A)(*1*) of this section and is currently at Level A may elect to remain in Level A under paragraph (a)(4)(i)(A)(*1*) of this section for all subsequent performance years of the agreement period.

(*i*) To be eligible to participate under Level A of the BASIC track as described in this paragraph, the ACO must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track under paragraph (a)(4) of this section, and is not participating in an agreement period under the BASIC track as a renewing ACO (as defined at § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under paragraph (a)(4) of this section; and the ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20).

(*ii*) A voluntary election by an ACO under this paragraph (a)(4)(i)(C)(*3*) must be made in the form and manner and by a deadline established by CMS.

(*iii*) The ACO's election to remain in Level A applies for the entirety of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*4*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*5*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(C)(*4*) of this section, the agreement is terminated.

(*6*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(C)(*2*) of this section applies to all subsequent performance years of the agreement period.

* * * * *

(e) For performance years beginning on or after July 1, 2019 and before January 1, 2024, CMS monitors low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period in the BASIC track, for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. If the ACO meets the definition of a high revenue ACO (as specified in § 425.20)—

* * * * *

(g) For agreement periods beginning on or after January 1, 2024, CMS

determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(i) An ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of two agreement periods, as specified in paragraph (a)(4)(i)(C) of this section.

(ii) An ACO that enters an agreement under the BASIC track's glide path at either Level A under paragraph (a)(4)(i)(A)(*1*) of this section or Level B under paragraph (a)(4)(i)(A)(*2*) of this section is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following:

(A) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(B) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(iii) An ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path as specified in paragraph (a)(4)(i)(C) of this section may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(h)(1) For performance years beginning on or after January 1, 2024, CMS monitors ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to an election under paragraph (a)(4)(i)(B)(*2*)(*vi*), paragraph (a)(4)(i)(B)(*2*)(*vii*), or paragraph (a)(4)(i)(C)(*3*) of this section for changes to their certified list of ACO participants that would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

(2) If the ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (under § 425.20)—

(i) The ACO is permitted to complete the performance year for which it met the definition of experienced with performance-based risk Medicare ACO initiatives in a one-sided model of the BASIC track, but is ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives. The ACO will be automatically advanced to Level E within the BASIC track under paragraph (a)(4)(i)(A)(*5*) of this section at the start of the next performance year and will remain in Level E for all subsequent performance years of the agreement period; and

(ii) Prior to entering performance-based risk, the ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b), in accordance with paragraph (a)(4)(i)(B)(*2*)(*v*) of this section or paragraph (a)(4)(i)(C)(*4*) of this section, as applicable. If the ACO fails to meet the requirements to participate under performance-based risk, the agreement is terminated in accordance with paragraph (a)(4)(i)(B)(*3*) of this section or paragraph (a)(4)(i)(C)(*5*) of this section, as applicable.

■ 64. Amend § 425.601 by—

■ a. Revising the section heading, and paragraphs (a)(1)(i) and (c)(2)(i);

■ b. Removing paragraph (d)(3);

■ c. In paragraph (f)(5)(ii), by removing the reference ''paragraph (f)(4)(i) of this section'', and adding in its place the reference ''paragraph (f)(5)(i) of this section''; and

■ d. In paragraph (f)(5)(iv), by removing the references ''paragraphs (f)(1) and (2) of this section'', and adding in their place the references ''paragraphs (f)(1) through (3) of this section''.

The revisions read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

* * * * *

(a) * * *

(1) * * *

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(c) * * *

(2) * * *

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

* * * * *

■ 65. Amend § 425.605—

■ a. By revising paragraph (a) introductory text, paragraphs (a)(1)(i) and (ii), paragraph(a)(2) introductory text, and paragraphs (a)(5)(i) and (a)(6);

■ b. By adding paragraph (b)(2)(ii)(E);

■ c. By revising paragraphs (b)(3), and (c)(2);

■ d. In paragraph (d)(1) introductory text, by removing the reference ''§ 425.600(d)'' and adding in its place the references ''§ 425.600(d) or § 425.600(g)'';

■ e. By revising paragraph (d)(1)(i)(A)(*2*) introductory heading;

■ f. By adding paragraphs (d)(1)(i)(A)(*3*) and (*4*);

■ g. By revising paragraph (d)(1)(i)(B)(*1*);

■ h. By revising the paragraph heading of paragraph (d)(1)(ii)(A)(*2*);

■ i. By adding paragraphs (d)(1)(ii)(A)(*3*) and (*4*);

■ j. By revising paragraph (d)(1)(ii)(B)(*1*);

■ k. By revising the paragraph heading of paragraph (d)(1)(iii)(A)(*2*);

■ l. By adding paragraphs (d)(1)(iii)(A)(*3*) and (*4*);

■ m. By revising paragraph (d)(1)(iii)(B)(*1*);

■ n. In paragraph (d)(1)(iii)(D)(*2*), by removing the reference ''§ 425.601'' and adding in its place the references ''§ 425.601 or § 425.652'';

■ o. By revising the paragraph heading of paragraph (d)(1)(iv)(A)(*2*);

■ p. By adding paragraphs (d)(1)(iv)(A)(*3*) and (*4*);

■ q. By revising paragraph (d)(1)(iv)(B)(*1*);

■ r. In paragraph (d)(1)(iv)(D)(*2*), by removing the reference ''§ 425.601'' and adding in its place the references ''§ 425.601 or § 425.652'';

■ s. By revising the paragraph heading of paragraph (d)(1)(v)(A)(*2*);
■ t. By adding paragraphs (d)(1)(v)(A)(*3*) and (*4*);
■ u. By revising paragraph (d)(1)(v)(B)(*1*);
■ v. In paragraph (d)(1)(v)(D)(*2*), by removing the reference ''§ 425.601'' and adding in its place the references ''§ 425.601 or § 425.652'';
■ w. In paragraph (d)(2), by removing the reference ''§ 425.600(d)'' and adding in its place the references ''§ 425.600(d) or § 425.600(g)''; and
■ x. By adding paragraph (h).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) *General rules.* For each performance year, CMS determines whether the estimated average per capita Medicare Parts A and B fee-for-service expenditures for Medicare fee-for-service beneficiaries assigned to the ACO are above or below the updated benchmark determined under § 425.601 or § 425.652, as applicable. In order to qualify for a shared savings payment under the BASIC track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section except as provided in paragraph (h) of this section.

(1) * * *

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(1)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(2) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(2) of this section exceeds this cap. If the cap described in paragraph (a)(1)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(2) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(1)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(1)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(2) of this section. To calculate aggregate growth in demographic risk scores or prospective HCC risk scores, as applicable, CMS does the following:

(*1*) Multiplies the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by the applicable proportion of total historical benchmark dollars associated with that population.

(*2*) Sums the amounts determined in paragraph (a)(1)(ii)(C)(*1*) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(2) In risk adjusting the benchmark as described in §§ 425.601(a)(10) and 425.652(a)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

* * * * *

(5) * * *

(i) These calculations exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(6) In order to qualify for a shared savings payment, the ACO's average per capita Medicare Parts A and B fee-for-service expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section except as provided in paragraph (h) of this section.

(b) * * *

(2) * * *

(ii) * * *

(E) Automatic transition from Level A to Level E of the BASIC track's glide path under § 425.600(h)(2).

(3) Except as provided in paragraph (h) of this section, in order to qualify for a shared savings payment, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below its updated benchmark by at least the MSR established for the ACO.

* * * * *

(c) * * *

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must—

(i) Meet either the minimum savings rate requirement established under paragraph (b) of this section, or the criteria described in paragraph (h) of this section;

(ii) Meet either the quality performance standard or alternative quality performance standard established under § 425.512; and

(iii) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) * * *

(1) * * *

(i) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO

that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(i)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(ii) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(ii)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(iii) * * *

(A) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iii)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(iv) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* * * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as

provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iv)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(v) * * *

(A) * * *

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) * * *

(*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(v)(A) of this section applies to an ACO's savings on a first dollar basis.

* * * * *

(h) *Calculation of shared savings for certain BASIC track ACOs not meeting MSR requirement.* An ACO that does not meet the minimum savings rate requirement established under paragraph (b) of this section but meets the other criteria described in paragraphs (c)(2)(ii) and (iii) of this section may qualify for a shared savings payment as provided in this paragraph.

(1) To qualify for a shared savings payment under this paragraph, an ACO must meet all of the following criteria:

(i) The ACO has average per capita Medicare Parts A and B fee-for-service expenditures for the performance year below the updated benchmark determined under § 425.652.

(ii) The ACO is a low revenue ACO as defined in § 425.20 as determined at the time of financial reconciliation for the performance year.

(iii) The ACO has at least 5,000 assigned beneficiaries for the relevant performance year as determined at the time of financial reconciliation for the performance year.

(iv) The ACO is participating in an agreement period beginning on January 1, 2024, or in subsequent years.

(2) The ACO's shared savings payment will be calculated as described in paragraph (d) of this section according to the ACO's applicable level of the BASIC track with the exception that the final sharing rate applied will equal one-half of the applicable percentage described in paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), or (d)(1)(v)(A)(*4*) of this section.

■ 66. Amend § 425.610—

■ a. In paragraph (a) introductory text, by removing the references ''§ 425.601, § 425.602 or § 425.603'' and adding in its place the references ''§ 425.601, § 425.602, § 425.603, or § 425.652'';

■ b. By revising paragraphs (a)(2)(i) and (ii), (a)(3) introductory text, (a)(6)(i) and (d)(2) paragraph heading;

■ c. By adding paragraphs (d)(3) and (4);

■ d. By revising paragraph heading of paragraph (f)(2);

■ e. By adding paragraphs (f)(3) and (4); and

■ f. In paragraph (g), by removing the references ''§ 425.601, § 425.602 or § 425.603'' and adding in its place the references ''§ 425.601, § 425.602, § 425.603 or § 425.652''.

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(2) * * *

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(2)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(3) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(3) of this section exceeds this cap. If the cap described in paragraph (a)(2)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(3) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(2)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(2)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(3) of this section. To calculate aggregate growth in demographic risk scores or prospective HCC risk scores, as applicable, CMS does the following:

(*1*) Multiplies the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by the applicable proportion of total historical benchmark dollars associated with that population.

(*2*) Sums the amounts determined in paragraph (a)(2)(ii)(C)(*1*) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(3) In risk adjusting the benchmark as described in §§ 425.601(a)(10), 425.602(a)(9), 425.603(c)(10), and 425.652(a)(10) CMS makes separate adjustments for each of the following populations of beneficiaries:

* * * * *

(6) * * *

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

* * * * *

(d) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(3) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(4) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

* * * * *

(f) * * *

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.*

* * *

(3) *For the performance year beginning on January 1, 2023.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established in § 425.512 applicable for the performance year by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i), or the alternative quality performance standard established in § 425.512(a)(4)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to § 425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(3)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in § 425.512 applicable for the performance year, the shared loss rate is 75 percent.

(4) *For performance years beginning on or after January 1, 2024.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established in § 425.512 applicable for the performance year by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i), or the alternative quality performance standard established in § 425.512(a)(5)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to § 425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(4)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in § 425.512 for the applicable performance year, the shared loss rate is 75 percent.

* * * * *

■ 67. Amend § 425.611—

■ a. In paragraph (c)(2)(i), by removing the references ''§§ 425.601(c) and 425.603(e)'' and adding in its place the references ''§§ 425.601(c), 425.603(e), and 425.654(a)'';

■ b. In paragraph (c)(2)(ii)(A), by removing the references ''§§ 425.601(a)(4), 425.602(a)(4), and 425.603(c)(4)'' and adding in its place the references ''§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4), and 425.652(a)(4)'';

■ c. In paragraph (c)(2)(ii)(B), by removing the references ''§§ 425.601(c)(3) and 425.603(e)(3)'' and adding in its place the references ''§§ 425.601(c)(3), 425.603(e)(3), and 425.654(a)(3)'';

■ d. By revising paragraph (c)(2)(iii);

■ e. In paragraph (c)(2)(v), by removing the reference ''§ 425.601(a)(5)(ii)'' and adding in its place the references ''§§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii)'';

■ f. In paragraph (c)(2)(v), by removing the reference ''§ 425.601(b)(2)'' and adding in its place the references ''§§ 425.601(b)(2) and 425.652(b)(2)(i)''; and

■ g. By revising paragraph (c)(4).

The revisions read as follows:

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID–19 pandemic.

(c) * * *

(2) * * *

(iii) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), and capping the prior savings adjustment according to § 425.652(a)(8)(iv).

* * * * *

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility for participation options according to § 425.600(d), and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

* * * * *

■ 68. Amend § 425.612 by—

■ a. Revising paragraph (a)(1)(i)(A) introductory text; and

■ b. In paragraph (a)(1)(i)(A)(*1*) by removing the phrase ''The communication plan'' and adding in its place the phrase ''A communication plan''.

The revision reads as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(i) * * *

(A) An attestation that it has established and will make available to CMS upon request the following narratives describing how the ACO plans to implement the waiver:

* * * * *

§§ 425.614 through 425.629 [Reserved]

■ 69. Section 425.630 is added to subpart G to read as follows:

§ 425.630 Option to receive advance investment payments.

(a) *Purpose.* Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs in order to support care improvement for underserved beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive advance investment payments as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO is not a renewing or a re-entering ACO.

(2) The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives.

(4) The ACO is a low revenue ACO.

(c) *Application procedure.* To obtain a determination regarding whether an ACO may receive advance investment payments, the ACO must submit to CMS complete supplemental information as part of its application to participate in the Shared Savings Program (filed pursuant to § 425.202) in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review.* (1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive advance investment payments. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The spend plan must:

(i) Describe how the ACO will spend its advance investment payments during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under this section.

(ii) Identify the categories of goods and services that will be purchased with advance investment payment funds (including any allowable uses under paragraph (e) of this section), the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS.

(iii) State that the ACO has established a separate designated account for the deposit and expenditure of all advance investment payments in accordance with paragraph (e)(4) of this section.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements for advance investment payments and will approve or deny the advance investment payment application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of advance investment payments.*

(1) *Allowable uses.* An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.

(2) *Prohibited uses.* Advance investment payments may not be used for any expense other than allowable uses under paragraph (e)(1) of this section. In the case of an ACO participating in Level E of the BASIC track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2).

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period.

(4) *Segregation of advance investment payments.* An ACO must segregate advance investment payments from all other revenues by establishing and maintaining a separate account into which all advance investment payments will be deposited immediately and from which all disbursements of such funds are made only for allowable uses in accordance with this paragraph.

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

(1) *Frequency of payments.* An ACO will receive the one-time payment at the beginning of Performance Year 1 of the ACO's agreement period. An ACO will receive quarterly payments each quarter for the first two performance years of the ACO's agreement period. An ACO may receive no more than eight quarterly payments.

(2) *Quarterly payment amount calculation methodology.* CMS does all of the following in determining the quarterly payment amount prior to the start of the quarter.

(i) Determines the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the quarterly payment amount are the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for an ACO under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for an ACO under prospective assignment), based on the certified ACO participant list for the relevant performance year.

(ii) Assigns each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS applies the following requirements in assigning a risk factors-based score:

(A) The risk factors-based score will be set to 100 if the beneficiary is dually eligible for Medicare and Medicaid.

(B) The risk factors-based score will be set to the Area Deprivation Index national percentile rank matched to the beneficiary's mailing address if the beneficiary is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an Area Deprivation Index national percentile rank.

(C) The risk factors-based score will be set to 50 if the beneficiary is not dually eligible for Medicare and Medicaid and sufficient data is not

available to match the beneficiary to an Area Deprivation Index national percentile rank.

(iii) Determines a beneficiary's payment amount. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

Risk factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	$0	$20	$24	$28	$32	$36	$40	$45

(iv) Calculates the ACO's quarterly payment amount. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii) of this section.

(g) *Recoupment and recovery of advance investment payments, and notice of bankruptcy.*

(1) CMS will recoup advance investment payments made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of advance investment payments made to the ACO. For both renewing and re-entering ACOs, CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of advance investment payments made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the advance investment payments previously recouped or otherwise repaid.

(3) Except as provided for in paragraphs (g)(4) of this section and § 425.316(e)(3), for each performance year, CMS will not recover an amount of advance investment payments greater than the shared savings earned by an ACO in that performance year.

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(5) In the event of bankruptcy— (i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Termination of advance investment payments.* (1) *General.* Except as provided in paragraph (h)(2) of this section, CMS may terminate an ACO's advance investment payments if the ACO–

(i) Fails to comply with the requirements of this section; or

(ii) Meets any of the grounds for ACO termination set forth in § 425.218(b).

(2) *Eligibility sanction.* CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO no longer meets the eligibility requirements specified in paragraphs (b)(3) and (b)(4) of this section.

(3) *No pre-termination actions.* CMS may immediately terminate an ACO's advance investment payments without taking any of the pre-termination actions set forth in § 425.216.

§§ 425.631 through 425.649 [Reserved]

■ 70. Section 425.650 is added to subpart G to read as follows:

§ 425.650 Benchmarking methodology.

(a) *Scope and purpose.* The methodology by which CMS establishes, adjusts, updates and resets an ACO's historical benchmark is described within this subpart G. The benchmarking methodology for agreement periods beginning before January 1, 2024, is specified in §§ 425.601, 425.602, and 425.603. The benchmarking methodology for agreement periods beginning on or after January 1, 2024, is specified in §§ 425.652 through 425.660.

(b) [Reserved]

■ 71. Section 425.652 is added to subpart G to read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on January 1, 2024, and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) This calculation includes individually beneficiary identifiable final payments made under a

demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under § 425.654 of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period, if applicable (as specified under § 425.658), or a combination of these two adjustments. CMS does all of the following to determine the adjustment(s) applied to the historical benchmark:

(i) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(ii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), the ACO will receive the regional adjustment to its benchmark as described in § 425.656.

(iii) If an ACO is eligible to receive a prior savings adjustment, CMS compares the pro-rated positive average per capita savings amount calculated in § 425.658(b)(3)(ii) with the regional adjustment described in § 425.656(c), expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

(A) If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings amount.

(*1*) If the sum is positive, the ACO will receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the positive sum and the cap described in paragraph (a)(8)(iv) of this section. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) If the sum is negative, the ACO will receive a reduced negative regional adjustment amount equal to the negative sum. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) If the regional adjustment, expressed as a single value, is positive, the ACO will receive an adjustment to the benchmark equal to the higher of the following:

(*1*) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings amount described in § 425.658(b)(3)(ii) and the cap described in paragraph (a)(8)(iv) of this section. The adjustment will be applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(iv) The cap on the prior savings adjustment calculated in either paragraph (a)(8)(iii)(A)(*1*) or paragraph (a)(8)(iii)(B)(*2*) of this section is equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month

calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.226(a)(1).

(iii) Redetermines the offset factor used in determining the negative regional adjustment amount under § 425.656(c)(4) and (5).

(iv) Redetermines the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology under subpart E of this part.

(v) In accordance with paragraph (a)(8) of this section, CMS redetermines the adjustment to the historical benchmark based on the redetermined regional adjustment (as specified under § 425.656), or the prior savings adjustment (as specified under § 425.658), or a combination of these two adjustments.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a) and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT).

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) CMS computes the two-way blend of national and regional growth rates as follows:

(i) Computes national growth rates using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(ii) Computes regional growth rates using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(B) Determine the ACO's regional expenditures as specified under § 425.654.

(iii) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year as specified in paragraph (b)(2)(iv) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(iv) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to the performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(3) CMS computes the ACPT as described in § 425.660.

(4) The two-way blend computed under paragraph (b)(2) of this section and the ACPT are blended together by taking a weighted average of the two.

(i) Absent unforeseen circumstances, the weight applied to the components of the blend is as follows—

(A) Two-way blend is equal to two-thirds; and

(B) ACPT is equal to one-third.

(ii) CMS has sole discretion to determine whether an unforeseen circumstance exists that warrants a reduction to the weight of the ACPT and the reduced weight that will apply to the ACPT.

(5) If an ACO's average per capita Medicare expenditures for the performance year are above its updated benchmark for the year determined as described in paragraph (b)(4) of this section by at least the MLR or negative MSR established for the ACO, CMS will compute a recalculated updated benchmark using the two-way blend described in paragraph (b)(2) of this section.

(i) If the ACO's average per capita Medicare expenditures for the performance year are above the recalculated updated benchmark by a smaller amount than the amount by which they are above the updated benchmark determined as described in paragraph (b)(4) of this section, CMS will use the recalculated updated benchmark to determine the following:

(A) The ACO's responsibility for sharing losses with the Medicare program for ACOs in two-sided models as described under §§ 425.605 and 425.610.

(B) The ACO's financial performance for purposes of monitoring ACO financial performance as described under § 425.316(d).

(ii) If the ACO's average per capita Medicare expenditures for the

performance year are below the recalculated updated benchmark, the ACO will neither be responsible for sharing losses with the Medicare program nor eligible for sharing in savings.

(c) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on January 1, 2024, and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) and (b) of this section except that rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

■ 72. Section 425.654 is added to subpart G to read as follows:

§ 425.654 Calculating county expenditures and regional expenditures.

(a) *Calculating county expenditures.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the assignment window corresponding to the relevant benchmark or performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(b) *Calculating regional expenditures.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by:

(1) Weighting the risk adjusted county-level fee-for-service expenditures determined under paragraph (a) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (b)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

■ 73. Section 425.656 is added to subpart G to read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This section applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculation of an average per capita expenditure amount for the ACO's regional service area.* To compute an average per capita expenditure amount for the ACO's regional service area, CMS does all of the following:

(1) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(2) Determines the ACO's regional expenditures as specified under § 425.654 for BY3.

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified using the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(c) *Calculation of the adjustment.* To calculate the adjustment, CMS does all of the following:

(1) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (b)(1) of this section and the average per capita amount of the ACO's historical benchmark determined under § 425.652(a)(1) through (7) and (c)(2), for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Applies a percentage, as determined in paragraph (d) of this section.

(3) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount equal to a percentage of

national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary. The cap is applied as follows:

(i) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(ii) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(4) For negative adjustments, CMS will multiply the regional adjustments calculated in paragraphs (c)(2) or (3) of this section by 1 minus an offset factor equal to the sum of the following—

(i) Proportion of the ACO's BY3 assigned beneficiaries that are dual eligible for Medicare and Medicaid; and

(ii) The difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and 1.

(5) The offset factor described in paragraph (c)(4) of this section is subject to a minimum value of zero (representing no offset to the negative regional adjustment) and a maximum value of 1 (representing a full offset to the negative regional adjustment).

(d) *Phase-in of weights used in regional adjustment calculation.*

(1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(1) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (d)(5)(i) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in § 425.652(a)(9), CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (d)(1) through (3) of this section used in calculating the regional adjustment.

(e) *Special rules for determining the weights used in the regional adjustment calculation for a re-entering ACO.* For a re-entering ACO whose prior agreement period benchmark was calculated according to § 425.603(c), CMS determines the weight used in the regional adjustment calculation described in paragraphs (b) through (d) of this section by considering the agreement period the ACO is entering into according to § 425.600(f) in combination with either of the following—

(1) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under § 425.603(c)(9) in its most recent prior agreement period; or

(2) For a new ACO identified as a re-entering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under § 425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

■ 74. Section 425.658 is added to subpart G to read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an adjustment to the historical benchmark to account for savings generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more performance

years in the Shared Savings Program during this period.

(b) *Calculate average per capita savings amount.* (1) Calculate total per capita savings or losses for each performance year during the 3 years prior to the start of the ACO's current agreement period. CMS applies the following requirements in determining the amount of per capita savings or losses for each performance year:

(i) Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with the requirements of this part, per capita savings for that year will be set to zero.

(iii) For a new ACO identified as re-entering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO's ACO participants were participating.

(2) Take the simple average of the per capita savings or losses calculated in paragraph (b)(1) of this section, including values of zero, if applicable.

(3) Determine the ACO's eligibility for the prior savings adjustment as follows:

(i) If the average per capita amount computed in paragraph (b)(2) of this section is less than or equal to zero, the ACO is not eligible to receive an adjustment for prior savings. The ACO will receive the regional adjustment to its benchmark as described in § 425.656.

(ii) If the average per capita amount computed in paragraph (b)(2) of this section is positive, apply a proration factor to account for any upward growth in the ACO's assigned population in the benchmark years of the ACO's current agreement period as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(c) *Applicability of the prior savings adjustment.* CMS compares the pro-rated average per capita savings amount determined in paragraph (b)(3)(ii) of this section with the regional adjustment described in § 425.656(c), to determine the applicability of the prior savings adjustment, the regional adjustment or a combination of these two adjustments in accordance with § 425.652(a)(8).

■ 75. Section 425.660 is added to subpart G to read as follows:

§ 425.660 Accountable Care Prospective Trend (ACPT).

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS incorporates a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period.

(b) *Determination of ACPT.* An ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. In determining the ACPT for an enrollment type for each performance year, CMS does all of the following:

(1) Projects per capita growth in Parts A and B fee-for-service expenditures for benchmark year 3 (BY3) and each performance year of the ACO's agreement period. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Aged/Disabled.

(2) Calculates one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(A) of this section (the ESRD ACPT) and one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(B) of this section (the Aged/Disabled ACPT). These annualized growth rates will remain fixed over the ACO's agreement period. The annualized growth rate is an annual rate of growth in projected expenditures during the ACO's 5-year agreement period relative to BY3, calculated as follows—

(i) Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period; or

(ii) If annualization as specified in paragraph (b)(2)(i) of this section is determined not to reasonably fit the anticipated growth curve, CMS will apply an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period.

(3) For each performance year, multiplies the applicable annualized growth rate described in paragraph (b)(2) of this section by BY3 truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the annualized growth rate as a flat dollar amount as follows:

(i) The ESRD ACPT is used for the ESRD population.

(ii) The Aged/Disabled ACPT is used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) Adjusts the flat dollar amounts described in paragraph (b)(3) of this section for each performance year for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

(5) Divides the risk adjusted flat dollar amounts described in paragraph (b)(4) of this section by the ACO's historical benchmark expenditures described in § 425.652(a) for each Medicare enrollment type to calculate the percent increase to be included in the blended update factor described in § 425.652(b)(4).

■ 76. Amend § 425.702 by adding paragraph (c)(2)(iii) to read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(2) * * *

(iii) As an organized health care arrangement (as defined at 45 CFR 160.103), and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

* * * * *

■ 77. Amend § 425.704 by—

■ a. Revising paragraph (b) introductory text; and

■ b. Adding paragraph (b)(3).

The revision and addition read as follows:

§ 425.704 Beneficiary-identifiable claims data.

* * * * *

(b) The ACO must certify that it is requesting claims data about any of the following:

* * * * *

(3) The patients of the organized health care arrangement (as defined at 45 CFR 160.103) in which the ACO is

participating with its ACO participants and ACO providers/suppliers, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

* * * * *

§ 425.800 [Amended]

■ 78. Amend § 425.800 in paragraph (a)(4) by removing the references ''§§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610'' and adding in its place the references ''§§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652''.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 79. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 80. Amend § 455.107 by revising paragraph (b)(1)(ii) to read as follows:

§ 455.107 Disclosure of affiliations.

* * * * *

(b) * * *

(1) * * *

(ii) *Change of selection.* A State may, in consultation with CMS, change its selection after it has been made from the option in paragraph (b)(2)(ii) of this section to that in paragraph (b)(2)(i) of this section.

* * * * *

Dated: July 1, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

Note: Except as otherwise noted in this proposed rule, previously finalized measures and specialty measures sets will continue to apply for the CY 2023 performance period/2025 MIPS payment year and future years. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF #/eCQM NQF #.

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TABLE Group A: New Quality Measures Proposed for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

A.1. Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Measure Steward:	American Academy of Dermatology
Numerator:	Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.
Denominator:	All patients aged 18 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.
Exclusions:	N/A
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses a gap in care for patients with psoriasis. This measure assesses for improvement of itch severity of symptoms from index visit to follow up visit, with an achieved score reduction of at least 2 points at follow up. This measure would represent another patient-reported outcome measure for interested parties to report within the MIPS Dermatology specialty set. This measure received conditional support for rulemaking from the Measures Application Partnership (MAP) pending Consensus-Based Entity (CBE) endorsement. While we agree with the MAP that CBE (for example, NQF) endorsement is preferred, we believe this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Here, guidelines of care for the management and treatment of psoriasis established by the Joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) recommend an itch severity assessment to appropriately assess the degree of pruritus when present.[1] We believe patient-reported outcome performance measures such as this measure ensure that patients and families are engaged partners in their care and can be an effective way to measure the quality of care provided by clinicians. Psoriasis is a common condition, with some 7.5 million people affected in the U.S., leading to millions of clinical visits every year (https://www.aad.org/media/stats-numbers). Chronic pruritis, the symptom assessed in this patient-reported outcome-based measure, has a significant impact on quality of life and is associated with depression and global distress, among other effects.[2] We believe that completion of the measure would support the creation of an effective treatment plan for the patient. Though the required assessment score reduction for this proposed new quality measure is lower than current AAD-NPF guidelines, the measure's current implementation as a MIPS Qualified Clinical Data Registry (QCDR) measure shows an aggregate performance score for this measure of 43.3 percent, indicating a gap in care for achieving 2 point or more reduction in itch severity. The denominator for this measure includes an initial index score for the numeric Rating Scale (NRS) and Visual Rating Scale (VRS) and the Itchy Quant assessment score of 4 or greater. This threshold indicates a clinically realistic goal for patients with an index score of 4 or more (minimal to moderate severity) and ensures capture of a more complete denominator eligible patient population to assess for an improvement in itch severity with psoriasis treatment. Additionally, the reliability performance score was high at 0.93 for the 2-point improvement from the index score. Therefore, we believe that incorporating this measure into MIPS would encourage measure adoption which would support clinician adherence to the AAD-NPF clinical guidelines, leading to better symptom control and improved quality of life for patients affected by chronic pruritis. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

[1] Elmets, C. A., Korman, N. J., Prater, E. F., Wong, E. B., Rupani, R. N., Kivelevitch, D., Armstrong, A. W., Connor, C., Cordoro, K. M., Davis, D., Elewski, B. E., Gelfand, J. M., Gordon, K. B., Gottlieb, A. B., Kaplan, D. H., Kavanaugh, A., Kiselica, M., Kroshinsky, D., Lebwohl, M., Leonardi, C. L., … Menter, A. (2021). Joint AAD-NPF Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures. Journal of the American Academy of Dermatology, 84(2), 432–470. https://www.jaad.org/article/S0190-9622(20)32288-X/fulltext.

[2] Lee, J., Suh, H., Jung, H., Park, M., & Ahn, J. (2021). Association between Chronic Pruritus, Depression, and Insomnia: A Cross-sectional Study. JAAD International, 3, 54-60. https://www.sciencedirect.com/science/article/pii/S2666328721000122.

A.2. Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessments performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Measure Steward:	American Academy of Dermatology
Numerator:	Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.
Denominator:	All patients aged 18 years and older, with a diagnosis of dermatitis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.
Exclusions:	N/A
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses a gap in care for patients with dermatitis. This measure assesses for improvement of itch severity of symptoms from index visit to follow up visit, with an achieved score reduction of at least 2 points at follow up. This measure would represent another patient-reported outcome measure for clinicians to report within the MIPS Dermatology specialty set. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE (for example, NQF) endorsement is preferred, we believe this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Chronic pruritis, the symptom assessed in this measure, has a significant impact on quality of life and is associated with depression, global distress, and sleep impairment among other effects (https://www.sciencedirect.com/science/article/pii/S2666328721000122). Though the required assessment score reduction for this proposed new quality measure is lower than current AAD guidelines (https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis), the measure's current implementation as a MIPS Qualified Clinical Data Registry (QCDR) measure shows an aggregate performance score for this measure of 54.9 percent, indicating a gap in care for achieving 2 point or more reduction in itch severity. The denominator for this measure includes an initial index score for the numeric Rating Scale (NRS) and Visual Rating Scale (VRS) and the Itchy Quant assessment score of 4 or greater. This threshold indicates a clinically realistic goal for patients with an index score of 4 or more (minimal to moderate severity) and ensures capture of a more complete denominator eligible patient populations to assess for an improvement in itch severity with dermatitis treatment. Additionally, reliability performance score was sufficient at 0.69 for the 2-point improvement from the index score. Therefore, we believe that incorporating this measure into MIPS would encourage measure adoption which would support clinician adherence to the AAD-NPF clinical guidelines, leading to better symptom control and improved quality of life for patients affected by chronic pruritis. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

A.3. Screening for Social Drivers of Health

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Measure Steward:	Physicians Foundation
Numerator:	Number of patients 18 and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Denominator:	Number of patients 18 years and older.
Exclusions:	N/A
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address health equity, an important topic that is currently not included within MIPS' quality measure inventory. This measure would assess the rate at which providers screen their adult patients for certain social drivers of health (DOHs); specifically, food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. Nearly all physicians within a recent survey indicated that their patients' health outcomes are affected by one or more DOH.[1] The most common DOHs experienced by the respondent physicians' patients were financial instability (34 percent) and transportation problems (24 percent).[1] Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health.[2] Thus, systematically screening patients for social determinants of health and referring them to community-based resources as needed can result in improved health outcomes.[2 3] Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being.[2 3] As an example, early findings from the Accountable Health Communities (AHC) model shows those patients within the 'Assistance Track' had 9 percent fewer emergency department visits as compared to their "control group counterparts during the first year following screening" (https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt). Adoption of this measure would address a significant performance gap as 84 percent of physician offices do not screen for all five needs.[4] Therefore, CMS has proposed this measure within the specialty sets of all clinician types to support those interested or already gathering DOH data. We believe the measure supports the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who choose to submit this measure. This measure is consistent with our priority to advance health equity throughout our various programs, including the Quality Payment Program. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive (https://www.cms.gov/pillar/health-equity). This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that endorsement of measures is preferred, we believe that the inclusion of this measure serves an important purpose in advancing quality measurement in MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Here, the U.S. Preventive Services Task Force (USPSTF), which is charged by section 915 of the Public Health Service Act to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations," specified the screening for key DOHs in its portfolio of recommendations (https://www.acpjournals.org/doi/10.7326/M20-0730). In a cross-sectional study, DOH were associated with 37.7 percent of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017, including both direct contributions and indirect contributions through other factors. DOH's direct contribution accounted for 5.8 percent of the variation after controlling for patient demographic characteristics, clinical risk, and supply of health care resources. These findings suggest that addressing DOH is important for reducing geographic spending variation and improving the value of health care. The evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[5 6] Another cross-sectional study found that screening for all five social needs was reported by 15.6 percent of practices, whereas 33.3 percent of practices reported no screening, suggesting that few US physician practices screen patients for all five key social needs associated with health outcomes.[4] We are also proposing a similar measure for the Hospital Inpatient Quality Reporting (IQR) Program. For further information on the Social Drivers of Health measure proposed for the Hospital IQR Program in the FY2023 IPPS/LTCH PPS proposed rule (https://www.govinfo.gov/content/pkg/FR-2022-05-10/pdf/2022-08268.pdf), we refer readers to 87 FR through 28498 through 28503. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

[1] Sullivan, T. (2022). New Report on Social Drivers of Health and Physician Practice. Policy & Medicine. https://www.policymed.com/2022/04/new-report-on-social-drivers-of-health-and-physician-practice.html.

[2] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. *Annals of Internal Medicine*, *168*(8), 577–578. https://doi.org/10.7326/M17-2441.

[3] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for HealthRelated Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at https:// doi.org/10.31478/201705b.

[4] Fraze, T. K., Brewster, A. L., Lewis, V. A., Beidler, L. B., Murray, G. F., & Colla, C. H. (2019). Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals. *JAMA network open*, *2*(9), e1911514. https://doi.org/10.1001/jamanetworkopen.2019.11514.

[5] Zhang, Y., Li, J., Yu, J., Braun, R. T., & Casalino, L. P. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*, *4*(6), e2113212. https://doi.org/10.1001/jamanetworkopen.2021.13212.

[6] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. https://doi.org/10.1001/jama.2020.13129.

A.4. Kidney Health Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.
Measure Steward:	National Kidney Foundation
Numerator:	Patients who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.
Denominator:	All patients aged 18-75 years with a diagnosis of diabetes at the start of the measurement period with a visit during the measurement period.
Exclusions:	Denominator Exclusions: 1. Patients with a diagnosis of End Stage Renal Disease (ESRD); 2. Patients with a diagnosis of Chronic Kidney Disease (CKD) Stage 5; 3. Patients who have an order for or are receiving hospice or palliative care.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it focuses on nephrology and the critical condition of diabetes, both identified as gaps within MIPS' quality measure inventory. We identified these gaps as priorities for future quality measures. This measure would replace and improve upon the existing measure Q119: Diabetes Medical Attention for Nephropathy. This measure is more specific than measure Q119 as it requires utilizing multiple tests, estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) tests, to assess a patient's kidney health. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE (for example, NQF) endorsement is preferred, we believe this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. Approximately 9 percent of American adults currently have CKD,[1] and it is projected that by 2030 approximately 17 percent of Americans aged 30 years and older will have CKD.[2 3] In the U.S. from 2002-2016, the burden of CKD, defined as years of life lost, years living with disability, disability-adjusted life years, and deaths, outpaced changes in the burden of disease for other conditions.[4] Patients with CKD are readmitted to the hospital more frequently than those without diagnosed CKD.[2] This public health issue is driven largely by the impact of diabetes—the most common comorbid risk factor for CKD.[2 4] The intent of this process measure is to improve rates of guideline-concordant kidney health evaluation in patients with diabetes. According to the American Diabetes Association (ADA) 'Standards of Medical Care in Diabetes', "Albuminuria and eGFR should be monitored regularly to enable timely diagnosis of CKD, [and] monitor progression of CKD…".[5] Higher rates of such evaluations are believed to improve the rate identification and, potentially, the treatment or delayed progression of CKD in this high-risk population. Early detection is critical in order to initiate timely care as the disease may silently progress to advanced stages (https://www.aafp.org/afp/2017/1215/p776.html). Annual kidney health evaluation in patients with diabetes to determine risk of CKD using estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) is recommended by clinical practice guidelines and has been a focus of various local and national health care quality improvement initiatives, including Healthy People 2020.[2] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

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A.5. Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Category	Description
NQF # / eCQM NQF #:	1662 / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.
Measure Steward:	Renal Physicians Association
Numerator:	Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period.
Denominator:	All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria.
Exclusions:	Denominator Exclusions: Patients receiving RRT.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this nephrology measure because it focuses on chronic kidney disease and diabetes. We have identified both conditions as gaps within MIPS and priority areas for future quality measurement. This measure received support for rulemaking by the MAP and was endorsed by the NQF (https://www.cms.gov/files/document/2022-muc-list-program-specific-measure-needs-and-priorities.pdf). This measure is intended to increase the number of patients receiving high-quality nephrology care by focusing on using clinically recommended CKD therapeutic interventions to treat diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria). Patients with these conditions who are treated with ACE inhibitors or ARB therapy have been shown to have lower rates of kidney failure, better cardiovascular outcomes, and lower mortality (https://pubmed.ncbi.nlm.nih.gov/23732715/). Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

A.6. Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
Numerator:	Patients with immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Denominator:	Patients, 18 years and older, with a diagnosis of cancer and on immune checkpoint inhibitors and who have grade 2 or above diarrhea and/or grade 2 or above colitis.
Exclusions:	Denominator Exclusions: Patients with pre-existing inflammatory bowel disease (IBD) (for example, ulcerative colitis, Crohn's disease).
Measure Type:	Process
Measure Domain:	Patient Safety (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses a gap in care and focuses on patient safety by enhancing early appropriate intervention for adverse effects experienced by patients diagnosed with cancer. If this proposed measure is finalized, it would represent the only quality measure in MIPS addressing gastrointestinal adverse effects from the use of immune checkpoint inhibitors as part of cancer treatment. This measure would address a gap in care for specific cancer types, leading to a potential increase in personalized care and informing quality improvement. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE (for example, NQF) endorsement is preferred, we believe this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. This measure's intent is to promote and assess for appropriate care for immune-related diarrhea and colitis, in accordance with recommendations by clinical guidelines addressing the topic of toxicities in immunotherapy. The occurrence of diarrhea and colitis can be a normal and treatable toxicity (and is many times not immune-related), but if it is immune-related, it can become life-threatening if not addressed in a timely manner.[1] Diarrhea and colitis are the second-most reported adverse events with immune checkpoint inhibitors. The measure is intended to support compliance with the clinical guidelines[2] by ensuring the eligible clinician is addressing the adverse event of diarrhea or colitis by immediately providing an intervention to prevent the adverse event from worsening. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

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A.7. Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.
Measure Steward:	College of American Pathologists
Numerator:	Surgical pathology reports that contain impression or conclusion of or recommendation for testing of MMR by immunohistochemistry, MSI by DNA-based testing status, or both.
Denominator:	All surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection.
Exclusions:	Denominator Exclusions: 1. Patients with an existing diagnosis of Lynch Syndrome. 2. Patients with an existing diagnosis of squamous cell carcinoma of the esophagus. 3. Hospice services provided to patient any time during the measurement period.
Measure Type:	Process
Measure Domain:	Communication and Care Coordination (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address a gap in care for pathology. The measure would assess for impression/conclusion of or recommendation for biomarker testing for specific cancer types, potentially leading to an increase in the rate of proper diagnosis. This proposed measure would represent a new quality measure clinical concept within the Pathology specialty set. This measure focuses on surgical pathology reports that contain impression or conclusion of or recommendation for testing of MMR by immunohistochemistry, MSI by DNA-based testing status, or both. The measure is fully tested and exhibited definitive reliability testing. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that the CBE (for example, NQF) endorsement is preferred, we believe this measure should nonetheless be added to MIPS and that it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity shall have a focus that is evidenced-based. This measure is intended to drive quality care, assessing for the efficient use of resources and promote increased use of personalized patient care and patient choice. Lynch syndrome can be attributed to 2-4 percent of all colorectal carcinomas and has clinical implications for treatment of the affected patient and family members.[1] [2] In the Molecular Biomarkers for the Evaluation of Colorectal Cancer guideline from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology it is recommended that mismatch repair status testing in patients with colorectal cancers is necessary for the identification of patients at high risk for Lynch syndrome and/or prognostic stratification.[1] One of two different initial tests can be performed on colorectal specimens to identify individuals who might have Lynch Syndrome: 1) Immunohistochemistry (IHC) for MMR protein expression, which is often diminished because of mutation; or 2) analysis for microsatellite instability (MSI), which results from MMR deficiency. The National Comprehensive Cancer Network (NCCN) guidelines state IHC and MSI on newly diagnosed colorectal and endometrial cancers regardless of family history to determine Lynch Syndrome, is cost effective and has been confirmed for colorectal cancer and endorsed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group at the CDC, the US Multi-Society Task Force on Colorectal Cancer, and the American Gastroenterological Association.[3] [4] In 2020, the average performance rate for the colorectal carcinoma only measure was 71.05 percent and the average performance rate for the endometrial carcinoma only measure was 76.63 percent. The detection of defective mismatch repair (MMR) or microsatellite instability (MSI) can assist with the proper diagnoses of cancer.[2] [5] Currently, there are no existing guidelines for the use of MMR/MSI for the detection of four cancer types (Colorectal Carcinoma, Endometrial, Gastroesophageal, and Small Bowel Carcinoma) and the potential utilization of Checkpoint Blockade Therapy. There are upcoming guidelines in development that will address these medical topics. This measure was developed to align with these guidelines to ensure it would drive quality outcomes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.

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A.8. Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System

Category	Description
NQF # / eCQM NQF #:	3612 / N/A
Quality #:	TBD
Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is the number of acute cardiovascular-related admissions per 100 person-years at risk for admission during the measurement year. Time at risk is calculated as the number of days a patient is alive, from the start of the measurement period or first visit, until heart transplantation, LVAD implantation, or home inotropic therapy; enrollment in hospice; death; or the end of the measurement period. Time not considered at risk and excluded: Days spent in a hospital, SNF, or acute rehabilitation facility; 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and Time during and after LVAD implantation, home inotropic therapy, or heart transplantation. Acute cardiovascular-related admissions are defined using individual ICD-10-CM codes and the Agency for Healthcare Research and Quality's (AHRQ) Clinical Classification Software (CCS) diagnosis categories, which group clinically similar codes together. AHRQ CCS diagnosis categories used to define outcome: 55: Fluid and electrolyte disorders; 96: Heart valve disorders; 97: Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease); 98: Essential hypertension; 100: Acute myocardial infarction; 102: Nonspecific chest pain; 104: Other and ill-defined heart disease; 105: Conduction disorders; 106: Cardiac dysrhythmias; 107: Cardiac arrest and ventricular fibrillation; 108: Congestive heart failure; non-hypertensive; 110: Occlusion or stenosis of precerebral arteries; 112: Transient cerebral ischemia; 115: Aortic; peripheral; and visceral artery aneurysms; 116: Aortic and peripheral arterial embolism or thrombosis; 157: Acute and unspecified renal failure; 245: Syncope. Subsets of the following AHRQ CCS diagnosis categories used to define outcome: 99: Hypertension with complications and secondary hypertension; 101: Coronary atherosclerosis and other heart disease; 103: Pulmonary heart disease; 109: Acute cerebrovascular disease; 114: Peripheral and visceral atherosclerosis; 117: Other circulatory disease; 130: Pleurisy; pneumothorax; pulmonary collapse; 131: Respiratory failure; insufficiency; arrest (adult); 133: Other lower respiratory disease; 237: Complication of device; implant or graft. The measure has several outcome exclusions: Planned admissions; Admissions from a skilled nursing facility (SNF) or acute rehab facility; Admissions within 10 days of discharge from a hospital, SNF, or acute rehab; Admissions after patient has entered hospice; Admissions before first visit to provider if no prior year visit; Admissions at time of or following: LVAD implantation, home inotropic therapy, or heart transplant.
Denominator:	The measure includes Medicare FFS beneficiaries ≥65 years of age with at least one inpatient principal diagnosis for heart failure/cardiomyopathy, or at least two outpatient or inpatient heart failure/cardiomyopathy diagnoses in any coding position (e.g., primary or secondary position) within the two years prior to the measurement year. • Beneficiaries must be enrolled full-time in Medicare Part A and B during the year prior to measurement and during the measurement period. Additionally, the cohort excludes: Patients with internalized left ventricular assist devices (LVADs); Patients with heart transplants; Patients on home inotropic therapy; Patients on hospice for any reason; Patients with end-stage renal disease (ESRD) – defined as chronic kidney disease stage 5 or on dialysis. Provider types included for measurement (vetted by TEP and Clinician Committee): Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants; Cardiologists: Cardiologists are covered by the measure because they provide overall coordination of care for patients with HF and manage the conditions that put HF patients at risk for admission due to acute cardiovascular-related conditions. Outcome attribution: We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a cardiologist, a PCP, or can be left unassigned. A patient who is eligible for attribution is assigned to a cardiologist if they have 2 or more visits with a single cardiologist, regardless of how many visits that patient has with a PCP. There are two scenarios where a patient can be assigned to a PCP. • First, if the patient has seen the PCP at least once but has no visits with a cardiologist, the patient is assigned to the PCP. • Second, if the patient has seen the PCP two or more times and has only one visit with a cardiologist, the patient is assigned to the PCP. If the patient has 1 visit each with a cardiologist and a PCP, the patient is assigned to the cardiologist. If the patient has 1 visit with a cardiologist and no visit with a PCP, the patient is assigned to the cardiologist. Finally, the patient will be unassigned if they had no visits with a PCP or cardiologist. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. Patients "follow" their clinician to the TIN designated by the clinician (that is, they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level.
Exclusions:	Numerator Exclusions: The measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of HF patients: Planned admissions (utilizes the adapted planned admission algorithm (PAA) to identify and exclude admissions that are planned); Admissions that likely do not reflect the quality of heart failure management provided by ambulatory clinicians including: Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility ("10-day buffer period"); Admissions that occur while patients are enrolled in Medicare's hospice benefit; Admissions that occur prior to the first visit with the assigned clinician. Admissions on the date or after any of the following: LVAD implantation, home inotropic therapy, or heart transplant (censored at the time of transition to advanced care).

Category	Description
	Denominator Exclusions: The measure excludes: 1. Patients without continuous enrollment in Medicare Parts A and B for the duration of the measurement period. 2. Patients who (or until death), were ever in hospice during the year prior to the measurement year or in hospice at the start of the measurement period. 3. Patients who have had no Evaluation & Management (E&M) visits to a MIPS eligible clinician. 4. Patients who have had a heart transplant, been on home inotropic therapy, or who have had a left ventricular assist device (LVAD) placed.
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims
Measure-Specific Case Minimum/Performance Period:	MIPS eligible clinicians, groups, subgroups*, virtual groups, and APM Entities containing at least 1 cardiologist / 21 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We are proposing this measure because heart failure (HF) is a leading cause of hospitalization in the United States and a major source of disease burden among older adults. There is strong evidence that ambulatory care clinicians can influence admission rates by providing high quality of care to patients with heart failure/cardiomyopathy (https://pubmed.ncbi.nlm.nih.gov/22665827/). We originally proposed this measure in the CY 2022 PFS proposed rule for the CY 2022 performance period/2024 MIPS payment year for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities but did not finalize this proposal or adopt the measure (86 FR 65692 through 65694). Key reasons for not finalizing the measure were concerns related to how beneficiaries would be attributed to clinicians and concerns about the appropriateness of risk adjustment for severity of heart failure (86 FR 65692 through 65694). We have subsequently worked to mitigate these concerns, and we are now re-proposing this measure for the CY 2023 performance period/2025 MIPS payment year to be initially reported only for MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities that include at least 1 cardiologist. After CY 2023, we would consider expanding reporting of this measure to include both cardiologists and PCPs. This HF measure was included on the 2020 Measures Under Consideration (MUC) list and evaluated by the MAP, which did not support the measure for rulemaking with potential for mitigation citing NQF endorsement and an analysis of the appropriateness of the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. We agree that NQF endorsement of measures is preferred, and this measure was subsequently submitted for NQF endorsement as part of the spring 2021 cycle and was endorsed by the NQF in January 2022. NQF currently serves as the CBE regarding certain performance measurement activities performed for CMS pursuant to sections 1890 and 1890A of the Act. We are proposing this administrative claims collection type outcome measure as HF is a leading cause of hospitalization in the United States and a major source of disease burden among the elderly population. Approximately 5.7 million adults in the United States have HF, costing the United States $30.7 billion each year, which includes the cost of health care services, medications for treatment, and missed days of work.[1] The toll on patients is also great, with high rates of hospitalization and mortality; nearly half of people with HF die within 5 years of their diagnosis.[2] Patients with chronic HF are vulnerable to a range of complications that may put them at risk for hospitalization, including worsening of HF symptoms and destabilization due to other conditions, such as respiratory disease or infection. To expand the list of available reporting options for clinicians, we are proposing this HF measure for use in MIPS, as it is an administrative claims measure, which has no reporting burden. Another version of this measure specified for Accountable Care Organizations (ACOs), "Risk-standardized Acute Admission Rates for Patients with Heart Failure" (ACO-37, NQF ID 2886) was previously used in the CMS Medicare Shared Savings Program, initially for accountability and currently as an informational measure. Although concerns have been raised about the appropriateness of risk adjustment, the measure accounts for patients with more complicated or severe heart failure in several ways: by excluding patients at advanced stages of heart failure, such as those with implanted left ventricular assist device (LVAD), those who receive home inotropic therapy, or those with prior heart transplant or with end stage renal disease; by risk adjusting for AICDs (defibrillators), systolic heart failure, comorbidities (including chronic kidney disease), and for frailty/disability. Moreover, the measure does not include advanced heart failure/transplant specialists for attribution. We conducted analyses of the appropriateness of risk adjustment which demonstrated that the risk adjustment model performed well across deciles of predicted admission risk. Based on this information and the material presented to the MAP and subsequently to the NQF, we believe the measure is evidence-based and would provide important information to drive improvements in clinical practice for heart failure patients. In order to mitigate concerns about risk adjustment for clinicians with higher caseloads of patients with more complex heart failure, the measure would be initially reported only for MIPS eligible cardiology TINs (i.e., MIPS TINs with at least one cardiologist) with a 21patient case minimum. We believe this approach would allow clinicians and groups who would be scored on the measure to become familiar with the measure. Note: Refer to the 2020 MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

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A.9. Adult Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Submission Criteria 1: Patients in Denominator 1 (D1) who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period. Submission Criteria 2: Patients in D2 who received at least 1 Td vaccine or 1 Tdap vaccine between 9 years prior to the encounter and the end of the measurement period. Submission Criteria 3: Patients in D3 who received at least 1 dose of the herpes zoster live vaccine or 2 doses of the herpes zoster recombinant vaccine anytime on or after the patients' 50th birthday. Submission Criteria 4: Patients in D4 who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine, on or after their 60th birthday and before the end of the measurement period.
Denominator:	Submission Criteria 1: Patients 19 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 2: Patients 19 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 3: Patients 50 years of age and older on the date of the encounter with a visit during the measurement period. Submission Criteria 4: Patients 66 years of age or older on the date of the encounter with a visit during the measurement period.
Exclusions:	Denominator Exclusion: All submission criteria: Active chemotherapy during the measurement period; or Bone marrow transplant during the measurement period; or History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time during the patient's history prior to or during the measurement period; or In hospice or using hospice services during the measurement period
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(v) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this multiple performance rate measure because it supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. Evidence provided by the measure steward testing indicates a gap in performance with average performance rates of 24 percent for influenza; 35 percent for Td or Tdap; 28 percent for zoster; and 17 percent for pneumococcal. This robust measure assesses the quality of clinical actions regarding the administration of the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines. The immunizations included within this measure would work to reduce the prevalence of severe diseases that may be associated with hospitalization and potentially lead to a decrease in overall health care costs. We believe the measure would improve overall vaccination rates more effectively than the current individual MIPS measures, Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults because performance is based on the administration of all four vaccinations rather than focusing on just one vaccination per measure. The measure would set a more stringent performance standard by requiring a set of adult immunizations in one composite measure compared to the prior framework, under which the administration of each vaccine was reported through a separate quality measure. In connection with the proposal of this measure, we are also proposing to remove measures Q110 and Q111 from traditional MIPS, while retaining those two measures for use in relevant MVPs as discussed under Table Group CC and retaining measure Q110 for the purposes of Shared Savings Program ACOs reporting through the APM Performance Pathway (APP) as discussed in section III.G.4.c.(1) of this proposed rule. We originally proposed this measure in the CY 2020 PFS proposed rule for the CY 2020 performance period/2022 MIPS payment year but did not finalize this proposal due to eminent changes to the pneumococcal vaccination guidelines (84 FR 63207 through 63209). We are now proposing this measure for the CY 2023 performance period/2025 MIPS payment year since it reflects the updated guidelines to include any pneumococcal conjugate vaccine or polysaccharide vaccine. Healthy People 2020—an initiative under the Office of Disease Prevention and Health Promotion that provides science-based, 10-year national objectives for improving the health of all Americans—recommends increasing the percentage of adults who are vaccinated against influenza, zoster, and pneumococcal disease.[1] The CDC Advisory Committee in Immunization Practices (ACIP) makes evidence-based recommendations for vaccine use. This measure encourages compliance with the recommendations by showing how many adults within the population receive vaccines per guideline recommendations (https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html). This measure would incentivize higher rates of adoption of the ACIP's recommendations. We propose that submission of all 4 performance rates would be required for this measure and would be used to determine data completeness. Submission of all 4 performance rates would align with current clinical guidelines as clinicians should attempt to administer to the appropriate patient population all vaccines this measure would assess for compliance. By requiring submission of all 4 performance rates, we would capture a complete data set to show performance gaps in vaccine administration. If this measure is finalized for inclusion within MIPS, we are proposing to score this measure using a weighted average for the first 2 years of implementation. Beginning with the CY 2025 performance period/2027 MIPS payment year, we

Category	Description
	would score this measure as an all-or-none composite measure to ensure a more thorough assessment of a patient's vaccination status.

[1] U.S. Department of Health and Human Services (2017). HealthyPeople.gov 2020 Topics & Objectives: Immunization and Infectious Diseases.

Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.

TABLE Group B: Previously Finalized Specialty Measures Sets Proposed for Combination and Proposed Modifications to Previously Finalized Specialty Measures Sets for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

We are proposing to add "Psychiatry" to the title of the Mental/Behavioral Health specialty set to create a combined new specialty set: Mental/Behavioral Health and Psychiatry (see Table B.21). We are also proposing to add "Optometry" to the title of the Ophthalmology specialty set to create a combined new specialty set: Ophthalmology/Optometry (see Table B.28). For both Ophthalmology/Optometry and Mental/Behavioral Health and Psychiatry Specialty Measures sets, there are no proposed changes to the measures contained within each specialty measures set. However, based upon interested parties' feedback and the overlap in denominator eligibility of both individual specialties, we are revising the specialty measures set titles to better reflect the applicable and appropriate MIPS eligible clinician types.

We are proposing to modify the below previously finalized specialty measures sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table Group B as follows: NQF # / eCQM NQF #.

We are proposing in section IV.A.10.c.(1)(b)(i) to expand the definition of a high priority measure at §414.1305 to include health equity measures. Further details of these types of measures are located in the CMS Measures Management System Blueprint Version 17.0 (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf).

Note: The CMS Web Interface collection type is no longer available in MIPS, except for the purposes of APM entities reporting through the APM Performance Pathway (APP), starting with the CY 2023 performance period; therefore, this collection type is no longer listed in any specialty sets under Table Group B. The CMS Web Interface collection type will remain through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the APP, see sections III.G.4.b.(9) and III.G.4.c.(1) of this proposed rule. For information on changes to measures under the CMS Web Interface collection type proposed for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this proposed rule.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET

Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title And Description	Measure Steward
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.1. Allergy/Immunology								
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**IIIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	IIealth Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population IIealth	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Allergy/ Immunology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Allergy/Immunology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Anesthesiology specialty set.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

MEASURES PROPOSED FOR **ADDITION** TO THE ANESTHESIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Anesthesiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ANESTHESIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Audiology specialty set.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	2152/ N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would help to broaden the patient population being screened for unhealthy alcohol use. There is known risk of adverse effects on the auditory system due to alcohol consumption making this an important aspect of care for audiologists.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Audiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE AUDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Cardiology specialty set.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association	We propose to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type. Given the close correlation of cardiovascular diseases and cerebral perfusion, interdisciplinary care is vital. We agree with interested parties' feedback that this measure would help to incentivize timely initiation of appropriate thrombolytic therapy for patients with stroke, which is an important component of cardiology care.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Cardiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Cardiology specialty set as it is generally clinically relevant to this clinician type, for those cardiologists that do not subspecialize. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Electrophysiology Cardiac Specialist specialty set.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.4b. Electrophysiology Cardiac Specialist

MEASURES PROPOSED FOR **ADDITION** TO THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Electrophysiology Cardiac Specialist specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Certified Nurse Midwife specialty set.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Certified Nurse Midwife specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / Ecqm NQF #	**Quality #**	**CMS Ecqm ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, Ecqm Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Chiropractic Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Clinical Social Work specialty set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association /American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINCAL SOCIAL WORK SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Clinical Social Work specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v11	eCQM Specifications	Outcome	Community /Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v12	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.8. Dentistry

MEASURES PROPOSED FOR **ADDITION** TO THE DENTISTRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Dentistry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
*	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS 138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS 50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology	We propose to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this is an important patient-centered measure that helps to address any changes in the patient's quality of life during treatment of psoriasis. This measure incorporates the patient voice, empowering patients to make the best-informed decisions about their own healthcare while also allowing clinicians to optimally adjust care as needed. See Table A.1 for rationale.
! (Outcome)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessments performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology	We propose to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this is an important patient-centered measure that helps to address any changes in the patient's quality of life during treatment of dermatitis. This measure incorporates the patient voice, empowering patients to make the best-informed decisions about their own healthcare while also allowing clinicians to optimally adjust care as needed. See Table A.2 for rationale.

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Dermatology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DERMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Community and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance

B.10. Diagnostic Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Diagnostic Radiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS14 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS16 1v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.11. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0069/ N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance	We propose to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would help decrease the overuse of antibiotics for the treatment of upper respiratory infections. The addition of this measure to this specialty set is feasible given the high rates that patients are assessed, treated, and managed for this condition in the emergency care setting.
* §	N/A/ N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that it is imperative to complete depression screenings in the emergency care setting to identify mental health conditions as well as forming appropriate treatment plans. Studies have shown depression to be more widespread in emergency departments than in the general public. Identifying patients with depression and their access to care in the emergency department is important as depression has been associated with poorer patient outcomes from care received in the emergency department, as well as increased length of stay in the emergency department and increased number of repeated emergency department visits (Abhar, et al., 2017).

B.11. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population HIealth	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We propose to include this measure in the Emergency Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that it is a significant public health concern, and as emergency medical professionals they can mitigate the consequences of alcohol abuse through screening, intervention, and referral. In turn, this would lower the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs.

B.11. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Emergency Medicine specialty set. as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Endocrinology specialty set.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50 85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS34 7v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS64 5v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Endocrinology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
	N/A/ N/A	TBD	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS13 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS14 5v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	2372 / N/A	112	CMS125v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Opioid)	N/A / N/A	305	CMS13 7v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS12 4v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v12	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v5	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive interested parties' engagement and comprehensive reviews of the literature.	The American Board of Family Medicine

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration that lies within this specialty's scope of practice. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.
* ! (Outcome)	N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that benign prostatic hyperplasia is a common medical condition that is frequently seen in family medicine practices. Including this measure would enhance patient-centered care amongst patients and their family medicine providers. Increasing the quality of comprehensive patient care can also result in the overall improvement of the patient's functional status.

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Family Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
	N/A/ N/A	TBD	CMS95 1v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.14. Gastroenterology

MEASURES PROPOSED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Gastroenterology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GASTROENTROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD):** Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	425	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.15 General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.15. General Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE GENERAL SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the General Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. Depression is a serious medical illness associated with higher rates of chronic disease, increased health care utilization, and impaired patient functioning. For the older patient population, depression is commonly diagnosed with other illnesses or as a side effect to medication. Proper depression assessment and intervention is important for the patients within the geriatric population.
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. Complications from patient falls are the leading cause of death from injury in people over the age of 65. Screening patients for their risk of future falls can help reduce the number of patients falls per year.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Geriatrics specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	CMS95 1v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.
	1662/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure is relevant to this specialist's patient population. Along with the high burden of cardiovascular morbidity and mortality in patients with chronic kidney disease, the fact that kidney function decreases in the normal aging process, and evidence that patients over the age of 60 have a greater likelihood of resistant hypertension without proper ACE or ARB therapy, this is an important and relevant measure for this specialty. See Table A.5 for rationale.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GERIATRICS SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.17. Hospitalists

MEASURES PROPOSED FOR **ADDITION** TO THE HOSPITALISTS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Hospitalists specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE HOSPITALISTS SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last IIIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS34 9v5	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would help decrease the overuse of antibiotics for the treatment of upper respiratory infections. The addition of this measure to this specialty set is feasible given the high rates that patients are assessed, treated, and managed for this condition within this specialty.
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that the appropriate use of antibiotics, including the avoidance of overuse of antibiotics, is an important quality of care consideration for infectious disease providers.
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration relevant to this specialty. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
* §	N/A / N/A	240	CMS117v11	eCQM Specifications	Process	Community/Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that appropriate childhood immunization is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that screening for hepatitis C infection is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that appropriate adolescent immunization is an important public health priority in reducing infectious disease incidence and is relevant to the scope of practice of infectious disease providers.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Infectious Disease specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INFECTIOUS DISEASE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v11	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161v11	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS16 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A / N/A	305	CMS137v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v12	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v5	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive interested parties' engagement and comprehensive reviews of the literature.	The American Board of Family Medicine

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that appropriate tuberculosis screening prior to initiation of biologic therapy is an important quality of care consideration relevant to this specialty. Proper screening helps ensure that treatment is not adversely affecting patients with an active infection.
* ! (Outcome)	N/A / N/A	476	CMS771v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that benign prostatic hyperplasia is a common condition among older men and inclusion of this measure in the internal medicine specialty set would promote patient-centered care with the goal of functional status improvement among primary care providers.

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Internal Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
	N/A/ N/A	TBD	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Interventional Radiology specialty set.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Interventional Radiology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERVENTIONAL RADIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.21. Mental/Behavioral Health and Psychiatry

As indicated in the introductory language of Table Group B of the appendix to this proposed rule, we are proposing to add "Psychiatry" to the title of the Mental/Behavioral Health specialty set to create a combined new specialty set: Mental/Behavioral Health and Psychiatry. The Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health and Psychiatry set, as well as comments on the proposal to create this combined set.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS12 8v11	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	N/A / 0104e	107	CMS16 1v11	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	366	CMS13 6v12	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS15 9v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS17 7v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication / Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Opioid)	N/A / N/A	305	CMS137 v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance	We propose to include this measure in the Mental/ Behavioral Health and Psychiatry specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback and the importance of including measures addressing substance use disorders, which are complex mental and behavioral health challenges. Inclusion of this measure would incentivize the appropriate screening and treatment for substance use disorders.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139 v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0 028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Nephrology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
	N/A/ N/A	TBD	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	1662/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association	We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that considering the high burden of cardiovascular morbidity and mortality in patients with chronic kidney disease, the decrease of kidney function in the normal aging process, and evidence that patients over the age of 60 have a greater likelihood of resistant hypertension without proper ACE or ARB therapy, validates the importance of this measure in the overall management of adult kidney disease. This measure is relevant and lies within the scope of care for this clinician type. See Table A.5 for rationale.
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEPHROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Neurology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.24. Neurosurgical

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROSURGICAL SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Neurosurgical specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROSURGICAL SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	239	CMS155v11	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that Hemoglobin A1c is an important factor in the determination of risk stratification and management strategies for individuals with prediabetes, and it is a typical clinical indicator in the management of diabetes care.
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Nutrition/Dietician specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NUTRITION/DIETICIAN SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	This measure is being proposed for removal from the Nutrition/Dietician specialty set. Per the measure specifications, the neurological lower extremity exam must consist of documentation of sensory abilities and should include 10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold; however, the clinician should perform all necessary tests to make the proper evaluation. We agree with interested parties' feedback that this clinician type lacks the required education and training to properly perform the quality action of this measure and it is out of the scope of their practice.
0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	This measure is being proposed for removal from the Nutrition/Dietician specialty set. Per the measure specifications, the proper evaluation of footwear must be completed, including a foot examination documenting the vascular, neurological, dermatological, and structural/biomechanical findings. The foot should also be measured using a standard measuring device, and counseling on appropriate footwear should be based on risk categorization. We agree with interested parties' feedback that this clinician type lacks the required education and training to properly perform the quality action of this measure and it is out of the scope of their practice.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v11	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v11	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v5	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type. Osteoporosis is an important public health issue requiring attention as it can lead to co-morbidities and decreased quality of life. Screenings are typically encouraged for women who are post-menopausal and, therefore, relevant to the patient population of this specialty.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Obstetrics/Gynecology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology/Hematology specialty set.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / 0389e	102	CMS129v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v11	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS64 5v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that depression screening and intervention is an essential care process for patients diagnosed with cancer, including patients with breast cancer. Depression can be a disabling co-morbidity in cancer patients and it's vital to incorporate this assessment and intervention in their comprehensive care.
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM specifications, MIPS CQMs specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance	We propose to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that medications used for supportive care for patients with cancer diagnoses, such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-effects and toxicity. Cancer care management between specialists heightens the need for closer collaboration of medication management for this patient population.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality	We propose to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that the inclusion of this patient-centered CAHPS survey measure can incentivize the evaluation of patient-centered domains relevant to cancer care (for example, timely care, provider communication, access to specialists, health promotion and education, shared decision making, functional status, care coordination).

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Oncology/Hematology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
	TBD	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)	We propose to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this patient-centered measure focuses on the appropriate management of adverse events that may reduce unnecessary utilization and improve quality of life (QOL) for patients taking checkpoint inhibitors. See Table A.6 for rationale.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Oncology/ Hematology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / 0389e	102	CMS12 9v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS15 7v11	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.27b. Radiation Oncology

MEASURES PROPOSED FOR **ADDITION** TO THE RADIATION ONCOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Radiation Oncology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.27b. Radiation Oncology

MEASURES PROPOSED FOR **ADDITION** TO THE RADIATION ONCOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Radiation Oncology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

As indicated in the introductory language of Table Group B of the appendix to this proposed rule, we are proposing to add "Optometry" to the title of the Ophthalmology specialty set to create a combined new specialty set: Ophthalmology/Optometry. The Ophthalmology/Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology/Optometry set, as well as comments on the proposal to create this combined set.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / 0086e	012	CMS143v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
	0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Ophthalmology/Optometry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	Patient Safety	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (TIIA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Orthopedic Surgery specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that the management and avoidance of surgical and post-surgical complications is a critical component of high-quality, patient-centered care. Post-operative complications after TIIA/TKA can delay a patient's recovery time, prolong hospitalizations, increase readmission rates, and increase disability or rates of mortality. Effective supportive care management can reduce the risk for complications, improve patient outcomes, and reduce overall healthcare costs. See Table A.8 for rationale.

B.29. Orthopedic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Orthopedic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	375	CMS66v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance	We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure is specific to chronic pharyngeal diagnoses that are commonly treated by the otolaryngology clinician type.
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM specifications, MIPS CQMs specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance	We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that medications should be assessed to ensure safe use among the older patient population. Reducing the number of inappropriate prescriptions can lead to improved patient safety and significant cost savings.
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons	We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that the measure includes specialty-specific coding (i.e., thyroid, parathyroid, etc. surgeries) and supports positive outcomes for otolaryngology surgical patients.

B.30. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Otolaryngology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.30. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0069 / N/A	065	CMS154v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance	This measure is being proposed for removal from the Otolaryngology specialty set. Per interested parties' feedback, the patients that fall within this measure's denominator are not typically treated by this clinician type. An otolaryngologist's practice focuses more on specific/chronic diagnosis coding rather than the diagnosis associated with this measure. This measure focuses on the appropriate treatment of the common cold which is not typical care that an otolaryngologist provides.
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pathology specialty set.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.31. Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.
! (Care Coordination)	TBD	TBD	TBD	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma:** Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both	College of American Pathologists	We propose to include this measure in the Pathology specialty set as it is clinically relevant to this clinician type. This measure addresses a gap in care regarding biomarker testing for specific cancer types. Biomarker testing is an important part of personalized medicine. It provides vital, individualized pathological data to clinicians utilized necessary for guidance in diagnosing and treating their patients, that can be tailored to the specific biomarkers that are found. See Table A.7 for rationale.

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	239	CMS155v11	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117v11	eCQM Specifications	Process	Community/ Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS137v11	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v11	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS136v12	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v11	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v11	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
§ ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication /Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pediatrics

MEASURES PROPOSED FOR ADDITION TO THE PEDIATRICS SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Pediatrics specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PEDIATRICS SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	379	CMS74v12	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Pediatrics specialty set beginning with the CY 2023 performance period/2025 MIPS payment year. Specialty specific coding is being removed from this quality measure for the 2023 performance period. Therefore, this measure is no longer relevant to this clinician type.

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.33. Physical Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Physical Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v11	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure falls within the scope of care for a physical or occupational therapist to assess patients for urinary incontinence symptoms during their medical history intake. Physical and occupational therapists are trained through their education and experience to assess for and treat various patient symptoms and conditions.
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that functional assessment tools can and should be completed by physical and occupational therapists for patients they are treating who are also diagnosed with rheumatoid arthritis. Physical and occupational therapists work with rheumatoid arthritis patients for physical therapy in both land-based and/or aquatic-based programs. These clinicians help to teach patients energy conservation techniques as well as gait, self-care and activities of daily living (ADL) techniques to reduce the stress and load on one's joints.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATONAL THERAPY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A/ N/A	128	CMS69v11	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.35. Plastic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE PLASTIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Plastic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139v11	eCQM Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Podiatry specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS12 5v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0034 / N/A	113	CMS130v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v5	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association	We propose to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that this measure complements other measures within their set. Adding this measure to this specialty set would elevate the importance of secondary prevention in cardiovascular disease.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Preventive Medicine specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	CMS95 1v1	eCQM specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmIIg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Pulmonology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PULMONOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
*	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Rheumatology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Rheumatology specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE RHEUMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS 145v1 1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS 144v1 1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS 156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.40. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028/0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee on Quality Assurance	We propose to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type. The addition of this quality measure to this specialty set reinforces the importance that all clinicians should be actively addressing tobacco use across all patient care settings. Decreasing the usage of tobacco would reduce risk of heart disease, lung disease and stroke, lower the prevalence of severe diseases that may be associated with hospitalization, and decrease overall health care costs.

B.40. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Skilled Nursing Facility specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.40. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	We propose to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type. It supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for the general population. This quality measure aligns with the evidence-based recommendations of the Advisory Committee on Immunization Practices (ACIP). Broadening immunization status awareness to this clinician type is valuable as it can help drive an increase in the adult immunization rates. The immunizations included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. See Table A.9 for rationale.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE SKILLED NURSING FACILITY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / N/A	110	CMS147v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.
N/A / N/A	111	CMS127v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group CC for rationale.

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.41. Speech Language Pathology

MEASURES PROPOSED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Speech Language Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS 138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons	We propose to include this measure in the Thoracic Surgery specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that thoracic surgeons are engaged in surgical procedures where appropriate management through supportive care can help decrease avoidable 30-day reoperation due to surgical complications. This measure would help incentivize appropriate management and avoidance of unnecessary and costly procedures.

B.42. Thoracic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Thoracic Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.43. Urgent Care

MEASURES PROPOSED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Urgent Care specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / 0389e	102	CMS129 v12	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v 11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645 v6	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771 v4	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
* ! (Appropriate Use)	N/A/ N/A	481	CMS646 v3	eCQM Specifications	Process	Effective Clinical Care	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A/ N/A	134	CMS2v12	Med Part B Cliams, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that depression screening and intervention is an essential care process for patients diagnosed with cancer, including patients with urological cancers. Depression can be a disabling co-morbidity in cancer patients and it's vital to incorporate this assessment and intervention in their comprehensive care.
* ! (Patient Safety)	0022/ N/A	238	CMS156v11	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class	National Committee for Quality Assurance	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that medications used for supportive care for patients with cancer diagnoses (including urological cancers), such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-effects and toxicity. Cancer care management between specialists (for example, urologists and oncologists) heightens the need for closer collaboration of medication management for this patient population.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that inclusion of this patient-centered CAHPS survey measure in this specialty set would incentivize evaluation of patient-centered domains relevant to urological cancer care (for example, timely care, provider communication, access to specialists, health promotion and education, shared decision making, functional status, care coordination).
* § ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that end-of-life care measures can provide meaningful feedback and create incentives to improve patient-centered, appropriate care to cancer patients, including patients with urological cancers. End-of-life care decisions may extend beyond oncologists to other specialty providers on the care team, including urologists for bladder or prostate cancers.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Outcome)	0216/ N/Λ	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. We agree with interested parties' feedback that end-of-life care measures can provide meaningful feedback and create incentives to improve patient-centered, appropriate care to cancer patients, including patients with urological cancers. End-of-life care decisions may extend beyond oncologists to other specialty providers on the care team, including urologists for bladder or prostate cancers.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Urology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A/ N/A	TBD	CMS951 v1	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	National Kidney Foundation	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. This measure focuses on nephrology and diabetes care. This measure encourages an annual visit where estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) results are reviewed in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidities of diabetes and chronic kidney disease. See Table A.4 for rationale.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0062 / N/A	119	CMS134v 11	MIPS CQMs Specifications, eCQM Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee of Quality Assurance	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
*	N/A / N/A	317	CMS22v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population IHealth	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v11	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.45. Vascular Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE VASCULAR SURGERY SPECIALTY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Screening for Social Drivers of Health:** Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Physicians Foundation	We propose to include this measure in the Vascular Surgery specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. Improving the clinician's understanding of the social obstacles their patients face can provide critical insight into predicting negative health outcomes and improving a patient's health status. Social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health. Therefore, screening patients for social drivers is a priority topic for us and we believe this quality measure should be implemented across the spectrum of clinician specialties. The addition of this quality measure to this specialty set reinforces our commitment that all clinicians should be actively engaging in activities that address the screening of social drivers of health of their patients and is in alignment with our priorities to support overall patient health. See Table A.3 for rationale, including clinical evidence supporting the proposal for inclusion of this measure in MIPS.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.
N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the CY 2023 performance period/2025 MIPS payment year. See Table Group C for rationale.

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 15 previously finalized quality measures from MIPS for the CY 2023 performance period/2025 MIPS payment year and future years under Table Group C. These measures are discussed in detail below. Our process measure removal criteria were discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) to implement an approach to incrementally remove process measures.

Under measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

Under Table Group CC, we propose to partially remove 2 additional measures from traditional MIPS and propose only to retain these 2 measures for MVP use and retain 1 of these measures for purposes of Shared Savings Program ACOs reporting through the APP.

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion that we use for the removal of measures includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent.

For a measure that is proposed for removal due to criteria relating to the benchmark and performance data, further information regarding MIPS benchmarking data can be located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

C.1. Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections

Category	Description
NQF # / eCQM NQF #:	2726 / N/A
Quality #:	076
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.2. Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality #:	119
CMS eCQM ID:	CMS134v11
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the Kidney Health Evaluation measure being proposed in Table A.4. The Kidney Health Evaluation measure focuses on patients with diabetes and encourages annual evaluation of estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR) to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidity of diabetes and CKD. The Kidney Health Evaluation measure, if finalized, would support the clinical conditions of kidney disease and diabetes, both identified as gaps within MIPS and considered priority areas for future measure development.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we propose to apply the following substantive changes to the measure specifications: 1) the initial patient population and the denominator exclusion for the eCQM Specifications collection type would be revised to change the age anchor from the start of the measurement period to the end of the measurement period so that it aligns with the HEDIS measure requirements and creates consistency for implementation across programs; 2) the logic and logic definitions related to hospice care for the eCQM Specifications collection type would also be updated to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely and 3) the denominator note for the MIPS CQMs Specifications collection type would be revised to asses the age for exclusions on the date of the encounter to reduce clinician burden and ensure alignment with guidelines when utilizing this collection type. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C. The substantive changes outlined above would be applied to the measure specifications.

C.3. Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	258
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.4. Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	260
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.5. Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	261
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.
Measure Steward:	Audiology Quality Consortium
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.6. Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.7. Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	275
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.8. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	323
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle (82 FR 53640). Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.87 percent for the MIPS CQMs Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and should be a standard of care. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.9. Functional Status Assessment for Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	375
CMS eCQM ID:	CMS66v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	eCQM Specifications
Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q470: Functional Status After Primary Total Knee Replacement. The process measure Q375 is only assessing whether pre- and post-assessments were completed; however, outcome measure Q470 requires a certain post-surgical PRO-PM score to meet performance.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we propose to apply the following substantive changes to the measure specifications: (1) the measure description would be revised to capture the measure intent and logic surrounding the age requirement to provide clarity and alignment across the header and logic; (2)the denominator exclusion would be updated so that the timing of the lower body fracture in relation to the THA would align with intent of exclusion; and (3)the logic and logic definitions related to hospice care would be updated to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C. The substantive changes outlined above would be applied to the measure specifications.

C.10. Photodocumentation of Cecal Intubation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	425
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.
Measure Steward:	American Society for Gastrointestinal Endoscopy
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because we believe this process measure represents performance outcomes that are clinically a standard of care and does not drive quality outcomes for patients.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.11. Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has a very low adoption rate which does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the 2023 PFS final rule, we propose that the measure denominator, denominator criteria and numerator options would be updated to align with USPSTF guidance that screening colonoscopies should start at age 45. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C. The substantive changes outlined above would be applied to the measure specifications.

C.12. Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0213 / N/A
Quality #:	455
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. Additionally, interested parties' feedback has consistently indicated that retrieval of data from the ICU is difficult, which makes this measure hard to submit. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.13. Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We propose the removal of this measure (finalized in 82 FR 53968) as a quality measure from MIPS because this measure is duplicative to measure Q459: Back Pain After Lumbar Discectomy/Laminectomy. We are proposing in Table D.65 substantive changes to measure Q459: Back Pain After Lumbar Discectomy/Laminectomy that would encompass the eligible patient population and clinical quality action represented within measure Q460.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.14. Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We propose the removal of this measure (finalized in 83 FR 60098 through 60099) as a quality measure from MIPS because this measure is duplicative to measure Q471: Functional Status after Discectomy/Laminectomy. We are proposing in Table D.69 substantive changes to measure Q471: Functional Status After Lumbar Discectomy/Laminectomy that would encompass the eligible patient population and clinical quality action represented within measure Q469.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

C.15. Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal	We propose the removal of this measure (finalized in 83 FR 60106) as a quality measure from MIPS because this measure is duplicative to measure Q461: Leg Pain After Lumbar Discectomy/Laminectomy. We are proposing in Table D.66 substantive changes to measure Q461: Leg Pain After Lumbar Discectomy/ Laminectomy that would encompass the eligible patient population and quality action represented within measure Q473.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the 2023 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C.

TABLE Group CC: Proposed Partial Removal of 2 Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These 2 Measures for Use in Relevant MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Beginning with the CY 2023 performance period/2025 MIPS payment year and future years, we propose to maintain measures Q110**:** Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults for MVP development and implementation, and maintain measure Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this proposed rule. We believe the clinical concepts represented by these MIPS quality measures would support some specialties in a more targeted approach rather than the broader clinical concept of multiple vaccinations represented within the proposed Adult Immunization Measure proposed under Table A.9 of this appendix. The tables within this section offer the rationale of the removal of measures Q110 and Q111 from traditional MIPS reporting.

Therefore, we are proposing to remove these 2 previously finalized quality measures from traditional MIPS due to the proposal of adding the Adult Immunization Status measure under Table A.9 of this appendix. We simultaneously propose to retain Q110 and Q111 for use in MVPs, and retain Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this proposed rule. See Table Group E for proposed changes to the CMS Web Interface collection type of this measure.

Measures Q110 and 111 are currently proposed as quality measures within the proposed Optimal Care for Kidney Health MVP (see Appendix 3: MVP Inventory Table A.2). Measure Q111 is available in the previously finalized Advancing Rheumatology Patient Care MVP (86 FR 66002).

We request comments on this proposal.

CC.1. Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / N/A
Quality #:	110
CMS eCQM ID:	CMS147v12
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we are proposing a more robust measure under Table A.9: Adult Immunization Status that would help improve complete vaccination rates for patients. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. However, the clinical quality action assessed within measure Q110 may be appropriate and applicable for some MVP topics where the proposed Adult Immunization Status measure may not be as it contains more clinical quality actions for assessment that may not apply to the clinician types submitting that MVP. Therefore, we propose the removal of this measure from traditional MIPS, but propose retention of this measure for use in relevant MVPs, and use by Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this proposed rule. See Table Group E for proposed changes to the CMS Web Interface collection type for this measure.
In the Circumstance the Measure is Retained	If measure A.9: Adult Immunization Status is not finalized for the CY 2023 performance period/2025 MIPS payment year and future years, we would retain measure Q110 in traditional MIPS in all relevant specialty sets under Table Group B. See Table Group DD for any substantive changes proposed for this measure.

CC.2. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	111
CMS eCQM ID:	CMS127v11
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we are proposing a more robust measure under Table A.9: Adult Immunization Status that would help improve complete vaccination rates for patients. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q111 only focuses on the administration of the pneumococcal vaccination rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Therefore, we propose the removal of this measure from traditional MIPS, but propose retention of this measure for use in relevant MVPs, because the clinical quality action assessed within measure Q111 may be appropriate and applicable for some MVP topics where the proposed Adult Immunization Status measure may not be as it contains more clinical quality actions for assessment that may not apply to the clinician types submitting that MVP.
In the Circumstance the Measure is Retained	If measure A.9: Adult Immunization Status is not finalized for the CY 2023 performance period/2025 MIPS payment year and future years, we would retain measure Q111 in traditional MIPS in all applicable specialty sets under Table Group B. See Table Group DD for any substantive changes proposed for this measure.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2023. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2023 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2024. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believe are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2023 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2023 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible would the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: The CMS Web Interface collection type is no longer available in MIPS, except for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period; therefore, this collection type is no longer listed in any tables under Table Group D. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the CMS Web Interface collection type for APP reporting, see sections III.G.4.b.(9) and III.G.4.c.(1) of this proposed rule. For information on changes to measures under the CMS Web Interface collection type proposed for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this proposed rule.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications| eCQM Specifications| MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-75 years of age by the end of the measurement period, with diabetes with a visit during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator criteria: For all collection types: Added:** coding for nutrition and dietitian. **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated numerator instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the guidance/numerator instructions for all collection types to remove "Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included" because it does not align with the intent of the measure, which is to ensure hemoglobin A1c control in all patients with any diagnosis of diabetes. These updates would allow the measure to better reflect its clinical intent, in accordance with the given diabetes diagnoses codes within the denominator criteria of the measure. We propose to update multiple components of the measure for the eCQM Specifications collection type so that the patient age is determined as of the end of the measurement period and aligns with Healthcare Effectiveness Data and Information Set (HEDIS) measure requirements and creates consistency in implementation. We propose to add encounter codes for MIPS eligible nutrition and dietitian clinicians, for all collection types, based upon interested parties' feedback, as they may provide nutrition counseling or therapy to patients to help manage diabetes and to ensure hemoglobin A1c control. The American Diabetes Association (ADA) emphasizes the need for medical nutrition therapy (MNT) as fundamental for diabetes management and the overall care plan.[1] "Strong evidence supports the effectiveness of MNT interventions provided by RDNs [registered dietitian nutritionist/registered dietitian] for improving A1C, with absolute decreases up to 2.0% (in type 2 diabetes) and up to 1.9% (in type 1 diabetes) at 3–6 months. Ongoing MNT support is helpful in maintaining glycemic improvements." [2] We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored, as this would allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

[1] Evert, A. B., Dennison, M., Gardner, C. D., Garvey, W. T., Lau, K., MacLeod, J., Mitri, J., Pereira, R. F., Rawlings, K., Robinson, S., Saslow, L., Uelmen, S., Urbanski, P. B., & Yancy, W. S., Jr (2019). Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report. *Diabetes care*, 42(5), 731–754. https://doi.org/10.2337/dci19-0014.

[2] Franz, M. J., MacLeod, J., Evert, A., Brown, C., Gradwell, E., Handu, D., Reppert, A., & Robinson, M. (2017). Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *Journal of the Academy of Nutrition and Dietetics*, 117(10), 1659–1679. https://doi.org/10.1016/j.jand.2017.03.022.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <=40% who were prescribed or already taking ACE inhibitor or ARB or ARNI therapy during the measurement period. **For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge. **Updated guidance: For the eCQM Specifications collection type: Revised:** This eCQM is to be reported as patient-based. To satisfy this measure, it must be reported for all heart failure patients at least once during the measurement period if seen in the outpatient setting. The requirement of two or more visits is used to establish that the eligible professional or eligible clinician has an existing relationship with the patient. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than or equal to 40% threshold noted in the denominator logic. A range that is greater than 40% would not meet the measure requirement. **Updated rate aggregation: For the eCQM Specifications collection type: Removed:** rate aggregation. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of heart failure. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria**: **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated denominator note: For the MIPS CQMs Specifications collection type**: **Revised:** LVEF threshold to <= 40%. **Updated denominator exclusion: For the eCQM Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD) prior to the end of the outpatient encounter with Moderate or Severe LVSD. **For the MIPS CQMs Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD). **Updated definition: For the eCQM Specifications collection type: Removed:** Prescribed-Inpatient setting: prescription given to the patient for ACE inhibitor or ARB or ARNI therapy at discharge OR ACE inhibitor or ARB or ARNI therapy to be continued after discharge as documented in the discharge medication list. **Revised:** LVEF threshold to <= 40%. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who were prescribed or already taking ACE inhibitor or ARB or ARNI therapy during the measurement period. **Updated denominator exception: For all collection types: Removed:** Documentation of system reason(s) for not prescribing ACE inhibitor or ARB or ARNI therapy (e.g., other system reasons).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and numerator language for the eCQM Specifications collection type by changing the "12-month" verbiage to "measurement period" to harmonize language with other MIPS quality measures for consistency and clarity in implementation. We propose to revise the description, numerator, and guidance, and to remove a definition and rate aggregation from the eCQM Specifications collection type in order to remove the inpatient population to resolve logic issues such as implementing two populations with different intended reporting frequencies. Additionally, we propose to revise the initial patient population to add clarity around the required number of qualifying encounters and to align with the measure logic. The measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We propose to update LVEF value for all collection types from <40 percent to <=40 percent to ensure all patients considered to have heart failure with reduced ejection fraction are included in the denominator, by including patients with a LVEF value of 40 percent, and add a denominator exclusion for patients with left ventricular assist device or a history of heart transplant, as these patients were not included in clinical treatment trials for low LVEF heart failure. We also propose the removal of the denominator exception for system reasons for all collection types as the medication is widely available.[1] These revisions would help to ensure a complete and appropriate patient population is being assessed for the quality action resulting in meaningful data.

Category	Description
	We propose to revise the numerator for the eCQM Specifications collection type to accurately reflect the clinical actions allowed in the current technical specification to ensure alignment between the measure logic, description, and numerator fields. Please note, if the revisions to the eCQM Specifications collection type are finalized, the MIPS version of the measure would not align with the NQF endorsed version of the measure.

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
NQF # / eCQM NQF #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator criteria: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove coding for Dressler's Syndrome from the denominator, as it is not a conclusive diagnosis to indicate coronary artery disease. Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with continued antiplatelet therapy, which would not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with antiplatelets (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision would ensure the patients captured within the measure denominator are appropriate.

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**The measure title is revised from 'Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)' to:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%). **The measure description is revised to read: For all collection types**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF <=40% who were prescribed beta-blocker therapy. **Updated instructions: For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated guidance**: **For the eCQM Specifications collection type: Revised:** LVEF threshold to <= 40%. . **Updated rate aggregation: For the eCQM Specifications collection type: Revised:** LVEF threshold to <= 40%. **The measure initial patient population is revised to read**: **For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of coronary artery disease. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria**: **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%. **Updated definition: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator note: For the MIPS CQMs Specifications collection type**: **Revised:** LVEF threshold to <= 40%. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure patients who satisfy both denominator eligibility criteria are only counted once. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update LVEF value from <40 percent to <=40 percent to better align with current clinical guidelines[1], and to ensure all patients considered to have heart failure with reduced ejection fraction are included in the denominator eligible patient population, by including patients with a LVEF value of 40 percent. This revision is reflected in the measure title, description, denominator, and definitions for all collection types; in the instructions, denominator criteria, and denominator note for the MIPS CQMs Specifications collection type; and in the guidance for the eCQM Specifications collection type. This would help to ensure a complete and appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to revise the initial patient population for the eCQM Specifications collection type to add clarity around the required number of qualifying encounters and to align with the measure logic. The measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We propose to update measure logic and logic definitions for the eCQM Specifications collection type to avoid counting a patient more than once if the patient satisfies both denominator criteria. This is in alignment with the guidance and the intent of the measure to only count patients who fit both denominator criteria in Population Criteria 1. We propose to remove coding for Dressler's Syndrome from the denominator for the MIPS CQMs Specifications collection type as it is not a as it is not a conclusive diagnosis to indicate coronary artery disease, which would align with revisions previously made to the eCQM Specifications collection type in the 2022 PFS final rule (86 FR 65895). Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with beta blocker therapy, which would not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with beta blocker therapy (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision would ensure the patients captured within the measure denominator are appropriate.

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications| MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type**: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <= 40% who were prescribed or already taking beta-blocker therapy during the measurement period. **For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge. **Updated guidance: For the eCQM Specifications collection type: Revised:** This eCQM is to be reported as patient-based. To satisfy this measure, it must be reported for all heart failure patients at least once during the measurement period. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than or equal to 40% threshold noted in the denominator logic. A range that is greater than 40% would not meet the measure requirement. Beta-blocker therapy: -For patients with prior LVEF <= 40%, beta-blocker therapy should include bisoprolol, carvedilol, or sustained release metoprolol succinate. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. **Updated rate aggregation: For the eCQM Specifications collection type: Removed:** rate aggregation. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** All patients aged 18 years and older with two qualifying encounters during the measurement period and a diagnosis of heart failure. **Updated denominator: For all collection types: Revised:** LVEF threshold to <= 40%. **Updated denominator exclusion: For the eCQM Specifications collection type: Added:** Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD) prior to the end of the outpatient encounter with Moderate or Severe LVSD. **For the MIPS CQMs Specifications collection type**: Patients with a history of heart transplant or with a Left Ventricular Assist Device (LVAD). **Updated definition: For the eCQM Specifications collection type: Removed:** Prescribed-Outpatient setting: prescription given to the patient for beta-blocker therapy at one or more visits in the measurement period OR patient already taking beta-blocker therapy as documented in current medication list. Prescribed-Inpatient setting: prescription given to the patient for beta-blocker therapy at discharge OR beta-blocker therapy to be continued after discharge as documented in the discharge medication list. **Revised:** LVEF threshold to <= 40%. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who were prescribed or already taking beta-blocker therapy during the measurement period. **Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** Beta-blocker Therapy definition LVEF threshold to <= 40%. **Updated denominator exception: For all collection types: Removed:** denominator exception for system reasons. **For the MIPS CQMs Specifications collection type: Revised:** LVEF threshold to <= 40%.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and numerator language for the eCQM Specifications collection type by changing the "12-month" verbiage to "measurement period" to harmonize the language with other MIPS quality measures for consistency and clarity in implementation of this measure. Additionally, we propose to revise multiple components of the eCQM Specifications collection type to include only the outpatient population, in an effort to resolve measure logic issues such as implementing two populations with different intended reporting frequencies. We propose to revise the initial patient population of the eCQM Specifications collection type to add clarity around the required number of qualifying encounters and to align with the measure logic. Measure logic requires patients to have 2 qualifying visits during the measurement period to establish that the eligible clinician has an existing relationship with the patient. We propose to update multiple components of the measure, across all collection types, to reflect an LVEF value of <=40 percent, to better align with current clinical guidelines, and to ensure all patients considered to have heart failure with reduced ejection fraction are included in the measure denominator, by including patients with a LVEF value of 40 percent, and add a denominator exclusion for patients with left ventricular assist device or a history of heart transplant as these patients were not included in

Category	Description
	clinical treatment trials for low LVEF heart failure.[1] These revisions ensure a clinically appropriate patient population is assessed for the quality action of prescribing beta-blocker pharmacotherapy resulting in meaningful data. We also propose the removal of the denominator exception for system reasons for all collection types as the medication is widely available. We propose to revise the numerator for the eCQM Specifications collection type to accurately reflect the clinical actions allowed in the current technical specification to ensure alignment between the measure logic, description, and numerator fields. Please note, if the revisions to the eCQM Specifications collection type are finalized, the MIPS version of the measure would not align with the NQF endorsed version of the measure.

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;*129*(16):e462]. *Circulation*, *126*(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.6 Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	009
CMS eCQM ID:	CMS128v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18 years of age and older as of April 30 of the measurement period who were dispensed antidepressant medications during the Intake Period, and were diagnosed with major depression 60 days prior to, or 60 days after the dispensing event and had a visit 60 days prior to, or 60 days after the dispensing event. **The measure definition is revised to read:** Intake Period: The 12-month window starting on May 1 of the year prior to the measurement period and ending on April 30 of the measurement period. Index Prescription Start Date (IPSD): The date of the earliest prescription dispensing event for an antidepressant medication during the Intake Period. The "continuous treatment" described in this measure allows for gaps in medication treatment up to a total 31 days during the 115-day period (numerator 1) or 52 days during the 232-day period (numerator 2). Gaps can include either gaps used to change medication, or treatment gaps to refill the same medication. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Numerator 1: Patients who have received antidepressant medication for at least 84 days (12 weeks) of continuous treatment beginning on the IPSD through 114 days after the IPSD (115 total days). Numerator 2: Patients who have received antidepressant medications for at least 180 days (6 months) of continuous treatment beginning on the IPSD through 231 days after the IPSD (232 total days).
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure definition to define and clarify the intake period. Additionally, to align with the updated definition, we propose to revise the initial patient population and patient age to ensure that patients meet the measure's age requirement. Additionally, we propose to update the logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored, as this would allow for different workflows and systems to align with exclusion criteria more closely ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We are proposing additional revisions to the language and logic to improve transparency of timing related to Index Prescription Start Date that would clarify that the continuous treatment period to include the IPSD, ensuring consistent implementation and improving readability.

D.7 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / 0086e
Quality#:	012
CMS eCQM ID:	CMS143v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.
Substantive Change:	**Updated value set/coding: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.

D.8 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	019
CMS eCQM ID:	CMS142v11
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the value set/coding for the eCQM Specifications collection type to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.

D.9 Screening for Osteoporosis for Women Aged 65-85 Years of Age

Category	Description
NQF # / eCQM NQF #:	0046 / N/A
Quality#:	039
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.
Substantive Change:	**Updated denominator criteria: For all collection types: Removed:** AND NOT Diagnosis of osteoporosis on date of encounter. **Updated denominator exclusion: For all collection types: Added:** diagnosis of osteoporosis on date of encounter. **Updated definitions: For all collection types: Added:** definition including coding for diagnosis of osteoporosis that would suffice.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to move the diagnosis of osteoporosis from the denominator criteria to a denominator exclusion. While this would not change the intent or intended patient population of the measure, it would clarify how to capture the denominator eligible patient population and ensure only patients who are appropriate for quality action assessment are included.

D.10 Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	050
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for occupational therapy.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding for occupational therapy to this measure as this measure is applicable to their scope of care. Non-surgical interventions can be utilized to improve quality of life for patients with urinary incontinence[1], which has been demonstrated in a preliminary study showing clinically significant improvement for patients receiving occupational therapy interventions.[2]

[1] Engberg, Sandra & Li, Hongjin. (2017). Urinary Incontinence in Frail Older Adults. Urologic Nursing. 37. 119. https://www.researchgate.net/publication/327898228_Urinary_Incontinence_in_Frail_Older_Adults.

[2] Cunningham, R., & Valasek, S. (2019). Occupational Therapy Interventions for Urinary Dysfunction in Primary Care: A Case Series. *The American Journal of Occupational Therapy*, 73(5), 7305185040p1-7305185040p8. https://doi.org/10.5014/ajot.2019.038356.

D.11 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** URI episodes when the patient had an active prescription of antibiotics (Table 1) in the 30 days prior to the episode date or is still active the same day of the encounter.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We propose to revise the denominator exclusion for the MIPS CQMs Specifications collection type to add clarity regarding those patients that should not be included within the denominator population due to active or previous antibiotic prescriptions, as this patient population would impact the performance calculated for the measure as the intent is to assess whether an antibiotic is prescribed.

D.12 Appropriate Testing for Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.
Substantive Change:	**The measure denominator instructions are revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. The intent is to determine whether antibiotics are being ordered appropriately. Antibiotics should only be ordered if a strep test has been performed to confirm a bacterial infection. Antibiotics should not be ordered for viral infections. Antibiotics should be ordered on the episode date through three days after the episode date. An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order during the measurement period. If a patient has more than one eligible episode in a 31-day period, include only the first eligible episode. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** The test must be performed to confirm a bacterial infection prior to the antibiotic order. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** timing of antibiotic to align with measure intent and current narrative for the denominator exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator and numerator instructions for the MIPS CQMs Specifications collection type to clarify the intent of the measure which is to ensure appropriate antibiotic dispensing following confirmation of a bacterial infection. We propose to update the logic and logic definitions for the eCQM Specifications collection type related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to align with exclusion intent and criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We propose to revise the denominator exclusion for the MIPS CQMs Specifications collection type to add clarity regarding those patients that should not be included within the denominator eligible patient population due to active or previously prescribed antibiotic. This patient population would impact the performance calculated for this measure as the intent is to assess that a group A streptococcus test is completed prior to prescribing an antibiotic. Patients actively on an antibiotic would most likely not benefit from this test due to the recommended treatment for the group A streptococcus infection is common, inexpensive antibiotics (https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html).

D.13 Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 0104e
Quality#:	107
CMS eCQM ID:	CMS161v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.
Substantive Change:	**The measure description is revised to read:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit. **Updated guidance: Revised:** This eCQM is an episode-based measure and should be reported for each instance of a new or recurrent episode of major depressive disorder (MDD) during the measurement period. This measure should be reported for each eligible encounter during which a new or recurrent episode of MDD is identified in adults that turn 18 or older during the measurement period. **The measure initial patient population is revised to read:** Patient visits for patients that turn 18 or older during the measurement period during which a new diagnosis of MDD, single or recurrent episode, was identified.
Measure Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the language for the measure description, guidance, and initial patient population to accurately capture the adult population by including patients that turn 18 years of age or older during the measurement period.

D.14 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Women 52-74 years of age by the end of the measurement period with a visit during the measurement period **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure, for the eCQM Specifications collection types, so that the patient age would be determined as of the end of the measurement period and aligns with HEDIS measure requirements and creates consistency in implementation. We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.15 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer. **The measure description is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer. **Updated stratification: For the eCQM Specifications collection type: Added:** Report a total rate, and each of the following age strata: Stratum 1: Patients age 46-49 by the end of the measurement period Stratum 2: Patients age 50-75 by the end of the measurement period **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 46-75 years of age by the end of the measurement period with a visit during the measurement period. **The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients 45-75 years of age with a visit during the measurement period **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patients 45 to 75 years of age on date of encounter. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and multiple measure components for all collection types to align with the 2021 U.S. Preventive Services Task Force (USPSTF) guidelines that recommend Colorectal Cancer Screenings begin at age 45 rather than beginning at age 50. We propose to add stratification for the eCQM Specifications collection type to monitor performance of the newly recommended 45-49 year age group, and to continue monitoring the previously established population of patients aged 50-75 years. We propose to update multiple components of the measure, for the eCQM Specifications collection type, so that the patient age is determined as of the end of the measurement period and aligns with the HEDIS measure requirements and creates consistency in implementation. We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.16 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated numerator instructions: Revised:** Table 1 - Antibiotic Medications by removing Erythromycin stearate, Erythromycin ethylsuccinate, and Erythromycin lactobionate from Macrolides AND Nitrofurantoin macrocrystals from Urinary anti-infectives.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator instructions in order to standardize the medication names.

D.17 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-75 years of age by the end of the measurement period, with diabetes with a visit during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66 and older by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it is extremely topped out and at the end of the topped-out lifecycle as finalized in 82 FR 53640. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. We propose to update multiple components of the measure, for the eCQM Specifications collection type, so that the patient age is determined as of the end of the measurement period and aligns with the HEDIS measure requirements and creates consistency in implementation. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes would be reflected within this collection type specification.

D.18 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0066 / N/A
Quality#:	118
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**The measure title is revised from 'Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)' to:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%). **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy. **Updated instructions: Revised:** LVEF threshold to <= 40%. **Updated denominator: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria: Revised:** LVEF threshold to <= 40%. **Updated denominator definition: Revised:** LVEF threshold to <= 40%. **Updated denominator criteria: Removed:** coding for Dressler's Syndrome.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure to reflect LVEF to <=40 percent to align with current clinical guidelines.[1] We also propose to remove coding for Dressler's Syndrome from the denominator as it is not a definitive diagnosis for CAD. Experts believe Dressler's syndrome, a form of secondary pericarditis with or without a pericardial effusion, is an immune system response following heart tissue and/or pericardium damage, which includes causes that may be outside of CAD, such as chest trauma. Additionally, this condition is not typically treated with ACE or ARB therapy, which would not be in alignment with the intent of this measure as it is assessing for the appropriate treatment of CAD with ACE or ARB therapy (https://www.ncbi.nlm.nih.gov/books/NBK441988/). This revision would ensure the patients captured within the measure denominator are appropriate.

[1] Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., Douglas, P. S., Foody, J. M., Gerber, T. C., Hinderliter, A. L., King, S. B., 3rd, Kligfield, P. D., Krumholz, H. M., Kwong, R. Y., Lim, M. J., Linderbaum, J. A., Mack, M. J., Munger, M. A., Prager, R. L., Sabik, J. F., … American College of Cardiology Foundation (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease: Executive Summary [Published Correction Appears in Circulation. 2014 Apr 22;129(16):e462]. *Circulation*, 126(25), 3097–3137. https://doi.org/10.1161/CIR.0b013e3182776f83.

D.19 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the performance period AND who had a follow-up plan documented if BMI was outside of normal parameters **Updated guidance: For the eCQM Specifications collection type: Revised:** BMI Measurement Guidance: * Height and Weight – An eligible professional or their staff is required to measure both height and weight. Both height and weight must be measured during the measurement period. Self-reported values cannot be used. * The BMI may be documented in the medical record of the provider or in outside medical records obtained by the provider. * If the documented BMI is outside of normal parameters, then a follow-up plan is documented during the encounter or during the measurement period. *If more than one BMI is reported during the measurement period, and any of the documented BMI assessments are outside of normal parameters, documentation of an appropriate follow-up plan will be used to determine if performance has been met. * Review the exclusions and exceptions criteria to determine those patients that BMI measurement may not be appropriate or necessary. Follow-Up Plan Guidance: * The documented follow-up plan must be based on the documented BMI, outside of normal parameters, example: "Patient referred to nutrition counseling for BMI above or below normal parameters." **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1. Patients who are pregnant at any time during the measurement period. 2. Patients receiving palliative or hospice care at any time during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Removed:** sort function. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients with a documented BMI during the encounter or during the measurement period, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the measurement period. **Updated numerator instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Height and Weight – An eligible clinician or their staff is required to measure both height and weight. Both height and weight must be measured within 12 months of current encounter. Self-reported values cannot be used. **Updated value set/coding: For the eCQM Specifications collection type: Added:** Plenity, Saxenda, Contrave, Naltrexone-bupropion, Benzphetamine, Phendimetrazine, and Wegovy to the "Medications for Above Normal BMI" value set (OID: 2.16.840.1.113883.3.526.3.1561).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and numerator for the eCQM Specifications collection type to correct the misalignment between the updated logic performed in 2021 and the measure description. Therefore, we are proposing to change the timing associated with BMI calculation and intervention to reduce implementation burden on clinicians. We also propose this change for the measure guidance for the eCQM Specifications collection type. We propose to revise the measure denominator exclusion language for the eCQM Specifications collection type to incorporate timing elements that we believe would improve clarity for implementation and reduce ambiguity. We propose to update the numerator instructions for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types to remove the language allowing for measurements to be obtained from separate encounters to ensure both height and weight are associated for utilization in obtaining a BMI. This would ensure the most accurate BMI is being assessed aligning with the intent of the measure, which is to screen all adults for BMI to initiate further evaluation and follow-up plan if necessary. We propose to update the value set/coding for the eCQM Specifications collection type by adding other weight loss management medications to the "Medications for Above Normal BMI" value set (OID: 2.16.840.1.113883.3.526.3.1561) for numerator compliance.

D.20 Documentation of Current Medications in the Medical Record

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	130
CMS eCQM ID:	CMS68v12
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **Updated guidance: For the eCQM Specifications collection type: Revised:** This list must include all known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements, cannabis/cannabidiol products AND must contain the medications' name, dosage, frequency and route of administration. **Updated numerator definition: For the MIPS CQMs Specifications collection types: Revised:** Current Medications – Medications the patient is presently taking including all prescriptions, over-the- counters, herbals, vitamins, minerals, dietary (nutritional) supplements, and cannabis/cannabidiol products with each medication's name, dosage, frequency and administered route. **Updated numerator note: For the MIPS CQMs Specifications collection types: Revised:** This list must include ALL known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements, cannabis/cannabidiol products AND must contain the medications' name, dosage, frequency and route of administration.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped-out lifecycle as finalized in 82 FR 53640. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. However, the benchmarking data continues to show a gap for the eCQM Specifications and MIPS CQMs Specifications collection types, as such, we propose to retain the measure for eCQM Specifications and MIPS CQMs Specifications collection types. We propose to update the guidance for the eCQM Specifications collection type, as well as the numerator note and numerator definition for the MIPS CQMs Specifications collection type to add recommendations to assess patient's usage of cannabis/cannabidiol/etc., as use of these drugs can affect the metabolization of other medications but is often not included in the medical record. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes would be reflected within this collection type specification.

D.21 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days (48 hours) after the eligible date of the qualifying encounter. **The measure description is revised to read: For the MIPS CQMs Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated guidance: For the eCQM Specifications collection type: Revised:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two days (48 hours) after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. **Updated definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for manic episodes to the denominator exclusions definition for bipolar depression. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days (48 hours) after the date of the qualifying encounter **The measure numerator is revised to read: For the MIPS CQMs Specifications collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Revised:** A depression screen is completed on the date of the encounter or up to 14 calendar days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two calendar days after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. An example to illustrate the follow-up plan documentation timing: if the encounter is on a Monday from 3-4 pm (day 0) and the patient screens positive, the clinician has through anytime on Wednesday (day 2) to complete follow-up plan documentation. **Added:** The follow-up plan MUST still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician or provider's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for manic episodes to the Bipolar Diagnosis value set (2.16.840.1.113883.3.600.450).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise multiple components of the measure for the eCQM Specifications and the MIPS CQMs Specifications Collection types to add a grace period after the end of the encounter to document the follow-up plan, which would allow more flexibility in the clinical workflow giving clinician's time for documentation. This would ensure that those clinicians who meet the intent of the measure, which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. We propose to update the measure definition for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to improve alignment with measure intent which is to screen for new cases of depression in patients who have never had a diagnosis of depression or bipolar disorder, as well as to clarify the timing requirements of diagnoses for the measure exclusions. We propose to add coding for manic episodes to the Bipolar Diagnosis value set for the eCQM Specifications collection type to align with measure intent.

D.22 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated denominator instructions: For the MIPS CQMs Specifications collection type: Added:** The two chemotherapy administrations must occur on different days within the timeframe of on or within 30 days before the denominator eligible encounter and on or within 30 days after the denominator eligible encounter. Two chemotherapy administrations performed on the same day will not meet the patient procedure requirement. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised: l**ogic to only apply lookback period for radiation treatment management code. **Revised:** logic related to chemotherapy treatments to further constrain the two unique chemotherapy treatments and data collection requirements to not extend beyond the measurement period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator instructions for the MIPS CQMs Specifications collection type and logic related to chemotherapy treatments for the eCQM Specifications collection type to clarify that two chemotherapy administrations performed on the same day would not meet the patient procedure requirement. Additionally, we propose to update the logic and logic definitions for the eCQM Specifications collection type to only apply lookback period for radiation treatment management code to meet the numerator intent of ensuring the intensity of pain experienced by patients is quantified during face-to-face or telehealth encounters, as required. This revision would also assist implementers in these instances, ensuring alignment with measure intent of quantifying a patient's pain severity so that those patients experiencing moderate to severe pain can be identified as the National Comprehensive Cancer Network (NCCN, 2021) suggests there is an undertreatment of pain in a subset of this patient population.

D.23 Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	145
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).
Substantive Change:	**The measure title is revised from 'Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy' to: For all collection types:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy **The measure description is revised to read: For all collection types:** Final reports for procedures using fluoroscopy that document radiation exposure indices. **Updated denominator criteria: For all collection types: Removed:** coding related to procedures that do not use fluoroscopy. **The measure numerator is revised to read: For all collection types:** Final reports for procedures using fluoroscopy that include radiation exposure indices. **The measure numerator definition is revised to read: For all collection types:** Radiation exposure indices – For the purposes of this measure, "radiation exposure indices" should include at least one of the following: 1. Reference air kerma (Ka,r) in Gy or mGy 2. Kerma-area product (PKA) or Dose area product (DAP) in uGy*m², mGy*cm² (or similar) 3. Peak skin dose (PSD) in Gy or mGy When reporting indices the report must clearly state what radiation quantity is being submitted, that is only reporting dose in mGy is insufficient. PSD in mGy is very different from Ka,r in mGy. As an example, PSD = 10 mGy or Ka,r = 10 mGy would meet numerator performance, but "10 mGy" alone would not. Note: When reporting reference air kerma or kerma-area product for biplane systems, the value should be reported as the sum of both planes (or the value for each plane should be reported individually). **The measure numerator instructions are revised to read: For all collection types:** **Documentation:** Dose information in the final report may be located in a variety of sources and should be available to the referring physician on receipt of report. **The measure numerator note is revised to read: For all collection types:** In interventional radiology procedures with runs, dose indices are displayed on the console and in the radiation dose structured report (RDSR). **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Radiation exposure indices documented in final report for procedure using fluoroscopy. **Performance Not Met:** Radiation exposure indices not documented in final report for procedure using fluoroscopy, reason not given.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise multiple components to better align with forthcoming AAPM Medical Physics Practice Guideline for Fluoroscopy Dose Management by Fisher, et al.[1] which indicates that exposure time and number of images is the least useful index for predicting potential tissue effects related to radiation exposure. Therefore, multiple components of the measure, across all collection types, would be updated to reflect the removal of exposure time and number of images as being numerator compliant. The measure steward indicated, and we believe it is reasonable, to expect practices providing fluoroscopy services to document one of the three accepted exposure indices in the radiology report, based upon the aforementioned guidelines. Additionally, we propose to revise the numerator definition to include the common units of measurement to emphasize our requirement that the report should include both the dose index AND the measurement. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[1] Fisher, R. F., Applegate, K. E., Berkowitz, L. K., Christianson, O., Dave, J. K., DeWeese, L., Harris, N., Jafari, M. E., Jones, A. K., Kobistek, R. J., Loughran, B., Marous, L., Miller, D. L., Schueler, B., Schwarz, B. C., Springer, A., & Wunderle, K. A. (2022). AAPM Medical Physics Practice Guideline 12.a: Fluoroscopy Dose Management. *Journal of Applied Clinical Medical Physics*, *23*(3), e13526. https://doi.org/10.1002/acm2.13526.

D.24 Tuberculosis Screening Prior to First Course Biologic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**The measure title is revised from 'Tuberculosis Screening Prior to First Course Biologic Therapy' to:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy. **The measure description is revised to read:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period. **Updated instructions: Revised:** This measure is to be submitted a minimum of once per performance period for patients who are being considered or prescribed a first course of a biologic and/or immune response modifier therapy seen during the performance period. **The measure denominator is revised to read:** All patients aged 18 years and older who are receiving a first course of therapy using a biologic and/or immune response modifier (such as kinase inhibitors) that includes a warning for potential reactivation of a latent infection. **Updated denominator criteria is revised to read:** Patient receiving first-time biologic and/or immune response modifier therapy. **Updated denominator instructions: Revised:** Patients are considered to be receiving a first course of therapy using a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection only if they have been prescribed such a biologic and/or immune response modifier during the performance period and also have not been prescribed any such biologic and/or immune response modifier in the 15 months preceding the encounter at which the biologic and/or immune response modifier was newly started. A biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection includes: **Added:** - Adalimumab-adbm (Cyltezo) - Adalimumab-atto (Amjevita) - Brodalumab (Siliq) - Risankizumab-rzaa (Skyrizi) - Tildrakizumab (Ilumya) **Revised:** The list of therapies is subject to change as new therapies are approved by the FDA. To be included in the denominator, patient must have an encounter and a prescription for a biologic and/or immune response modifier in the performance period (1/1/2023-12/31/2023) WITHOUT a prior prescription for a biologic and/or immune response modifier within the 15 months prior to the biologic and/or immune response modifier prescribed during the performance period. **The measure numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic and/or immune response modifier prescription. **Updated numerator options: Revised:** **Performance Met:** TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise multiple components of the measure to be more inclusive of non-rheumatology specialties so the measure may be used to evaluate additional clinician types, such as dermatology. We propose to revise the measure to include biologics rather than just immune response modifier therapies in order to support the variety of clinicians that may be able to report the measure. Additionally, we propose to revise the list of pharmacological agents that would meet the denominator criteria of the measure to more completely capture patients appropriate for the assessment of the quality action and intent of the measure, which is to ensure that all patients receiving a first course of biologic and/or immune response modifier that may cause latent TB reactivation are tested for TB appropriately.[1]

[1] Hasan, T., Au, E., Chen, S., Tong, A., & Wong, G. (2018). Screening and Prevention for Latent Tuberculosis in Immunosuppressed Patients at Risk for Tuberculosis: A Systematic Review of Clinical Practice Guidelines. *BMJ Open*, 8(9), e022445. https://doi.org/10.1136/bmjopen-2018-022445.

D.25 Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen. **The measure denominator is revised to read: For all collection types:** All patients aged 60 years and older. **Updated denominator criteria: For all collection types: Revised:** Patients aged ≥ 60 years on date of encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise multiple components of this measure for all collection types to include patients aged 60 years of age and older, which expands the intended patient population and allows clinicians to screen a broader patient population for elder maltreatment. The American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion in 2021 stating that ACOG "supports screening of patients older than 60 years to help identify victims of abuse and provide them with appropriate medical and psychosocial care and referrals (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/elder-abuse-and-womens-health)."

D.26 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**The measure description is revised to read:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies. **The measure numerator is revised to read:** Visits where patient has a documented current functional outcome assessment using a standardized tool AND a documented care plan based on the identified functional outcome deficiencies within two days of the assessment **Updated numerator definition: Revised:** Patient unable to participate in administration of the functional outcome assessment(s) within the 'Not Eligible (Denominator Exception)' definition. **Updated numerator instructions: Added:** The follow-up plan must still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record. **Updated numerator options: Revised:** **Performance Met:** Functional outcome assessment documented as positive using a standardized tool AND a care plan based on identified deficiencies is documented within two days of the functional outcome assessment. **Performance Met:** Functional outcome assessment using a standardized tool is documented within the previous 30 days and a care plan, based on identified deficiencies is documented within two days of the functional outcome assessment. **Performance Not Met:** Documentation of a positive functional outcome assessment using a standardized tool; care plan not documented within two days of assessment, reason not given.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure to allow flexibility in the clinical workflow by allowing two days following the functional outcome assessment for the clinician to document a care plan based on the identified deficiencies for their patients. This update was recommended by the American Physical Therapy Association (APTA). This would ensure that those clinicians who meet the intent of the measure, which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. Additionally, we propose to update the definition for 'Not Eligible (Denominator Exception)' to generalize the process of administering the assessment to the patient. Rather than only allowing an exception for patients who are unable to complete the assessment, the measure would allow the denominator exception to be utilized in clinical situations where the patient is not able to participate in the administration of the assessment. We also propose to add language to the numerator instructions to clarify the additional two-day documentation period and determine if the clinician meets the intent of the measure.

D.27 Stroke and Stroke Rehabilitation: Thrombolytic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	187
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic was initiated within 4.5 hours of time last known well. **Updated instructions: Revised:** This measure is to be submitted for each episode of acute ischemic stroke for patients who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic was initiated within 4.5 hours of time last known well. **The measure denominator is revised to read:** All patients aged 18 years and older with a diagnosis of acute ischemic stroke whose time of arrival is within 3.5 hours (≤210 minutes) of time last known well. **Updated denominator criteria: Revised:** Time last known well to hospital arrival less than or equal to 3.5 hours (≤ 210 minutes). **The measure numerator is revised to read:** Patients for whom IV thrombolytic therapy was initiated at the hospital within 4.5 hours (≤ 270 minutes) of time last known well. **Updated numerator note: Added:** Updated clinical practice guidelines recommend this extended timeframe for thrombolytics, however, earlier intervention is preferred and leads to better outcomes. Patients who are eligible for thrombolytics should receive treatment as quickly as possible after arrival at the hospital. **The measure numerator options are revised to read:** **Performance Met:** IV thrombolytic therapy initiated within 4.5 hours (≤ 270 minutes) of time last known well. **Denominator Exception:** IV thrombolytic therapy not initiated within 4.5 hours (≤ 270 minutes) of time last known well for reasons documented by clinician (e.g., patient enrolled in clinical trial for stroke, patient admitted for elective carotid intervention, patient received tenecteplase (TNK)). **Performance Not Met:** IV thrombolytic therapy not initiated within 4.5 hours (≤ 270 minutes) of time last known well, reason not given.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure to align with the 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association.[1] We propose to update the measure to reflect the updated guidelines for appropriate treatment with IV thrombolytic for the clinical situation when the patient presents with acute ischemic stroke. These updates would be consistently applied to multiple components throughout the measure and a numerator note would be added to address timeliness of intervention.

[1] Kleindorfer, D. O., Towfighi, A., Chaturvedi, S., Cockroft, K. M., Gutierrez, J., Lombardi-Hill, D., Kamel, H., Kernan, W. N., Kittner, S. J., Leira, E. C., Lennon, O., Meschia, J. F., Nguyen, T. N., Pollak, P. M., Santangeli, P., Sharrief, A. Z., Smith, S. C., Jr, Turan, T. N., & Williams, L. S. (2021). 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack: A Guideline from the American Heart Association/American Stroke Association. *Stroke, 52*(7), e364–e467. https://doi.org/10.1161/STR.0000000000000375.

D.28 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Added:** coding for traction retinal detachment to Table 1 "Retinal Detachment with Retinal Defect" coding. **Updated value set/coding: For the eCQM Specifications collection type: Added**: coding for heteronymous bilateral field defects to valueset "Visual Field Defects" (2.16.840.1.113883.3.526.3.1446) and tractional retina detachment to valueset "Retinal Detachment with Retinal Defect" (2.16.840.1.113883.3.526.3.1478).
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the denominator exclusion of this measure to include coding for traction retinal detachment. Additionally, we propose to update the value set for the eCQM Specifications collection type to encompass this update as well as heteronymous bilateral field defects. This would allow for better alignment with the intent of the denominator exclusions which remove eye conditions that may hinder the best corrected visual acuity of 20/40 or better within the 90 days following cataract surgery allowing a homogenous patient population to support equitable and clinically realistic outcomes. The expansion of the coding ensures the appropriate patient population is included within the denominator eligible patient population. We believe these significant ocular conditions, which can negatively impact the visual outcome of surgery, can also potentially impact a clinician's performance on this measure.

D.29 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Revised:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the FOTO LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definitions to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.30 Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the FOTO LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.31 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **LEPF PROM score:** The LEPF PROM score may be achieved using one of three forms: the FOTO LEPF PROM computer adaptive test, the FOTO LEPF PROM short form, or an alternative PROM score that is cross-walked to the LEPF PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **LEPF PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the LEPF PROM score as described in the introduction under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.32 Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Low Back FS PROM score:** The Low Back FS PROM score may be achieved using one of three forms: the FOTO Low Back FS PROM computer adaptive test, the FOTO Low Back FS PROM short form, or an alternative PROM score that is cross-walked to the Low Back FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets acceptable scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Low Back** FS **PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Low Back FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.33 Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Shoulder FS PROM:** The Shoulder FS PROM score may be achieved using one of three forms: the FOTO Shoulder FS PROM computer adaptive test, the FOTO Shoulder FS PROM short form, or an alternative PROM score that is cross-walked to the FOTO Shoulder FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Shoulder** FS **PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Shoulder PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definition to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.34 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. **Added:** **The Elbow/Wrist/Hand FS PROM score:** The Elbow/Wrist/Hand FS PROM score may be achieved using one of three forms: the FOTO Elbow/Wrist/Hand FS PROM computer adaptive test, the FOTO Elbow/Wrist/Hand FS PROM short form, or an alternative PROM score that is cross-walked to the FOTO Elbow/Wrist/Hand FS PROM, using a cross-walk form developed by the measure steward. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the **Elbow/Wrist/Hand FS PROM** score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition**: Revised: Functional Status (FS) Score – This is the Elbow/Wrist/Hand FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure definitions to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure. We propose to expand the denominator criteria of this measure to include encounters within a skilled nursing facility at the request of physiatrists who care for patients in the nursing home setting. We propose to revise the definition to provide clarity regarding the addition of the skilled nursing facility to the denominator criteria. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.35 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients who were screened for tobacco use AND 2) All patients who were identified as a tobacco user during the measurement period and who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period AND 3) All patients who were screened for tobacco use and, if identified as a tobacco user received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period, or identified as a tobacco non-user This measure contains three submission criteria which aim to identify patients who were screened for tobacco use (submission criteria 1), patients who were identified as tobacco users during the measurement period and who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period (submission criteria 2), and a comprehensive look at the overall performance on tobacco screening and cessation intervention (submission criteria 3). **Updated denominator: For the eCQM Specifications collection type: Revised:** Population 2: Equals Initial Population who were screened for tobacco use during the measurement period and identified as a tobacco user. **Updated denominator criteria: For all collection types: Added:** coding for nutrition and dietitian. **Updated denominator exclusion: For all collection types: Added:** denominator exclusion for all submission criteria for patients receiving hospice any time during the measurement period. **The measure definition is revised to read: For all collection types:** Tobacco Use – use of any tobacco product The 2021 USPSTF recommendation references the US Food and Drug Administration definition of tobacco which includes "any product made or derived from tobacco intended for human consumption (except products that meet the definition of drugs),

Category	Description
	including, but not limited to, cigarettes, cigars (including cigarillos and little cigars), dissolvables, hookah tobacco, nicotine gels, pipe tobacco, roll-your-own tobacco, smokeless tobacco products (including dip, snuff, snus, and chewing tobacco), vapes, electronic cigarettes (e-cigarettes), hookah pens, and other electronic nicotine delivery systems." The 2021 USPSTF recommendation describes smoking as generally referring to "the inhaling and exhaling of smoke produced by combustible tobacco products such as cigarettes, cigars, and pipes." The 2021 USPSTF recommendation describes vaping as "the inhaling and exhaling of aerosols produced by e-cigarettes." In addition, it states, "vaping products (i.e., e-cigarettes) usually contain nicotine, which is the addictive ingredient in tobacco. Substances other than tobacco can also be used to smoke or vape. While the 2015 USPSTF recommendation statement used the term 'electronic nicotine delivery systems' or 'ENDS,' the USPSTF recognizes that the field has shifted to using the term 'e-cigarettes' (or 'e-cigs') and uses the term e-cigarettes in the current recommendation statement. E-Cigarettes can come in many shapes and sizes, but generally they heat a liquid that contains nicotine (the addictive drug in tobacco) to produce an aerosol (or 'vapor') that is inhaled ('vaped') by users." Tobacco Cessation Intervention – Includes brief counseling (3 minutes or less), and/or pharmacotherapy – **For the eCQM Specifications collection type:** Note: Concepts aligned with brief counseling (e.g., minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the value set for the numerator. Other concepts such as written self-help materials (e.g., brochures, pamphlets) and complementary/alternative therapies are not included in the value set and do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Note: Concepts aligned with brief counseling (for example, minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the numerator. Other concepts such as written self-help materials (e.g., brochures, pamphlets) and complementary/alternative therapies do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **Updated numerator: For the eCQM Specifications collection type: Revised:** Population 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. Population 3: Patients who were screened for tobacco use at least once during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated numerator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. For Submission Criteria 3: Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 2 and Submission Criteria 3: language to reflect the tobacco cessation intervention needing to be completed during the measure period or in the six months prior. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For Submission Criteria 3: language to reflect the tobacco cessation intervention needing to be completed during the measure period or in the six months prior. **Updated denominator exception: For all collection types: Removed:** denominator exceptions for all submission criteria. **Updated value set/coding: For the eCQM Specifications collection type: Added:** Encounter Inpatient value set.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure for all collection types to better define and align the lookback period for tobacco cessation intervention and to allow a lookback of 6-months prior to the current measurement period. We propose to update the denominator statement for Population 2 for all collection types to clarify the timing of the screening for tobacco cessation intervention and to align with the logic timing in the eCQM Specifications collection type. We are proposing to update the denominator criteria to include encounter codes for MIPS eligible registered dieticians and nutritionists to allow them to screen for tobacco use as part of a comprehensive patient assessment. Additionally, we propose to add denominator exclusions for all collection types for patients receiving hospice care during the measurement period and remove all denominator exceptions. This would lessen clinician burden as those patients for whom it would not be appropriate to complete the quality action would be removed for the denominator eligible patient population. We also propose to update the measure definition to align with 2021 USPSTF recommendations. We propose to update the value set/coding for the eCQM Specifications collection type to include inpatient encounter codes as this patient population is appropriate for the denominator and should be assessed for the clinical quality action. Smoking increases the risk for many adverse health effects and though many patients that use tobacco abstain during hospitalization, they relapse upon discharge and as health crises can be a powerful motivator, this represents an important setting for completing tobacco cessation intervention.[1]

[1] Cummins, S. E., Gamst, A. C., Brandstein, K., Seymann, G. B., Klonoff-Cohen, H., Kirby, C. A., Tong, E. K., Chaplin, E., Tedeschi, G. J., & Zhu, S. H. (2016). Helping Hospitalized Smokers: A Factorial RCT of Nicotine Patches and Counseling. *American journal of preventive medicine*, *51*(4), 578–586. https://doi.org/10.1016/j.amepre.2016.06.021.

D.36 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Do not include BP readings taken during an acute inpatient stay or an ED visit. **Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-85 years of age by the end of the measurement period who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude patients 66 and older by the end of the measurement period who are living long term in a nursing home any time on or before the end of the measurement period. 2. Exclude patients 66-80 by the end of the measurement period with an indication of frailty for any part of the measurement period who also meet any of the following advanced illness criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior 3. Exclude patients 81 and older by the end of the measurement period with an indication of frailty for any part of the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated instructions and numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the measure guidance for the eCQM Specifications collection type to streamline and clarify language regarding blood pressure readings and which readings are appropriate to utilize for the purposes of assessing the quality action for this measure. Additionally, this revision would better align with the logic and intent of the measure which is to control high blood pressure in an effort to reduce adverse health effects such as cardiovascular disease and mortality. We propose to update multiple components of the measure, for the eCQM Specifications and MIPS CQMs Specifications collection types, so that the patient age is determined as of the end of the measurement period and would align with Healthcare Effectiveness Data and Information Set (HEDIS) measure requirements and creates consistency in implementation. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to update the numerator note for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types to provide additional guidance around multiple blood pressure readings taken on the same day. We propose to add language to all collection types to ensure that only distinct numeric results are being utilized for the purpose of this measure as ranges and thresholds do not meet the measure's intent.

D.37 Use of High-Risk Medications in Older Adults

Category	Description
NQF # / eCQM NQF #:	0022 / N/A
Quality#:	238
CMS eCQM ID:	CMS156v11
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Calculate average daily dose for each prescription event. To calculate average daily dose, multiply the quantity of pills prescribed by the dose of each pill and divide by the days supply. For example, a prescription for the 30-days supply of digoxin containing 15 pills, 0.25 mg each pill, has an average daily dose of 0.125 mg. To calculate average daily dose for elixirs and concentrates, multiply the volume prescribed by daily dose and divide by the days supply. Do not round when calculating average daily dose. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 65 years and older at the end of the measurement period who had a visit during the measurement period. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Added: For Submission Criteria 1: coding for hospital/hospital observation discharge, outpatient observation, inpatient, and emergency department. For Submission Criteria 2: coding for emergency department. **Updated definition: For the MIPS CQMs Specifications collection type: Added:** For Submission Criteria 1: • At least two high-risk medications from the same drug class in Table 3 on different dates of service, each exceeding average daily dose criteria. And Calculate average daily dose for each prescription event. To calculate average daily dose, multiply the quantity of pills prescribed by the dose of each pill and divide by the days supply. For example, a prescription for the 30-days supply of digoxin containing 15 pills, 0.25 mg each pill, has an average daily dose of 0.125 mg. To calculate average daily dose for elixirs and concentrates, multiply the volume prescribed by daily dose and divide by the days supply. Do not round when calculating average daily dose. **Added:** For the **definition** of 'Cumulative Medication Duration': Table 3: High-Risk Medications With Average Daily Dose Criteria. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** A prescription for medications classified as high risk exceeding average daily dose criteria listed in Table 3. **Updated definition: For the eCQM Specifications collection type: Revised:** Index Prescription Start Date (IPSD) – The start date of the earliest prescription ordered for a high-risk medication during the measurement period. A high-risk medication is identified by any one of the following: a. A prescription for medications classified as high risk at any dose and for any duration. b. A prescription for medications classified as high risk at any dose with greater than a 90 day supply. c. A prescription for medications classified as high risk exceeding average daily dose criteria. An order is identified by either a prescription order or a prescription refill. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Rate 1: Patients with at least two orders of high-risk medications from the same drug class on different days. a. At least two orders of high-risk medications from the same drug class. b. At least two orders of high-risk medications from the same drug class with summed days supply greater than 90 days. c. At least two orders of high-risk medications from the same drug class each exceeding average daily dose criteria. Rate 2: Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines) on different days. Total rate (the sum of the two previous numerators, deduplicated). **Updated value set/coding: For the eCQM Specifications collection type: Revised:** to group drugs by class rather than medication. **Added:** belladonna alkaloids, chlordiazepoxide-clidinium, glimepiride. **Removed:** naloxone/pentazocine, pentazocine, ticlopidine hydrochloride.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the initial patient population for the eCQM Specifications collection type to change the age anchor to the end of the measurement period so that it would align with HEDIS measure requirements and create consistency for implementation across programs. We propose to update the definition, guidance, and numerator language for the eCQM Specifications collection type to incorporate average daily dose criteria for determining the numerator submission criteria 1 option for submission. Additionally, we propose to revise the numerator language and correct the logic to account for at least two orders from same drug class rather than two orders of the same medication to support patient safety when prescribing high risk medications.

Category	Description
	We propose to update the definitions and numerator instructions for the MIPS CQM Specifications collection type to incorporate average daily dose criteria for determining the numerator submission criteria 1 option for submission and clarify calculations. We propose to update the definition for the eCQM Specifications collection type to add definition for 'order' to align with updates to the logic and to look for multiple orders OR an order with a refill for determining numerator submission criteria 2 option for submission. We propose to update logic and logic definitions related to hospice care for the eCQM Specifications collection type to add flexibility to how data may be captured or stored to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.38 Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	239
CMS eCQM ID:	CMS155v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.
Substantive Change:	**Updated stratification: Revised:** Stratum 1 – Patients age 3-11 years at the end of the measurement period Stratum 2 – Patients age 12-17 years at the end of the measurement period **The measure initial patient population is revised to read:** Patients 3-17 years of age by the end of the measurement period, with at least one outpatient visit with a primary care physician (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the stratification and initial patient population for the eCQM Specifications collection type to change the age anchor from the start of the measurement period to the end of the measurement period so that it aligns with HEDIS measure requirements and creates consistency for implementation across programs. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.39 Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	240
CMS eCQM ID:	CMS117v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**Updated guidance: Removed:** Numerator criteria includes evidence of receipt of the recommended vaccine or the following: -- DtaP: Adverse reaction to the DtaP or Td vaccine; or encephalopathy due to DtaP or Td vaccination -- Polio (IPV) vaccine: Adverse reaction to the IPV vaccine, streptomycin, polymyxin B, or neomycin -- MMR Vaccination: Immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; history of measles, mumps, or rubella; or a seropositive result for the antigens -- Hib: Adverse reaction to the Hib vaccine -- Hepatitis B: Seropositive result for the antigen, adverse reaction to the hepatitis B vaccine, adverse reaction to common baker's yeast, or a history of hepatitis B illness -- Chicken pox (varicella zoster): Seropositive result for the antigen; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; or a history of varicella zoster -- Pneumococcal: Adverse reaction to the pneumococcal vaccine -- Hepatitis A: Seropositive result for the antigen, adverse reaction to the hepatitis A vaccine, or a history of hepatitis A illness -- Rotavirus: Adverse reaction to the rotavirus vaccine, severe combined immunodeficiency, or a history of intussusception -- Influenza: Adverse reaction to the influenza vaccine; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; or adverse reaction to neomycin **Updated denominator exclusion: Added:** Exclude children with any of the following on or before the child's second birthday: • Severe combined immunodeficiency • Immunodeficiency • HIV • Lymphoreticular cancer, multiple myeloma or leukemia • Intussusception **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Diphtheria, tetanus, and pertussis (DtaP) vaccination Children with any of the following on or before the child's second birthday meet criteria: • At least four DtaP vaccinations, with different dates of service. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the diphtheria, tetanus or pertussis vaccine. • Encephalitis due to the diphtheria, tetanus or pertussis vaccine. Poliovirus vaccination (IPV) At least three IPV vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. Measles, mumps, and rubella vaccination (MMR) Children with either of the following meet criteria: • At least one MMR vaccination on or between the child's first and second birthdays. • All of the following anytime on or before the child's second birthday (on the same or different date of service): o History of measles o History of mumps o History of rubella Haemophilus influenzae type b vaccination (HiB) Children with either of the following meet criteria on or before the child's second birthday: • At least three HiB vaccinations, with different dates of service. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the HiB vaccine. Hepatitis B Children with any of the following on or before the child's second birthday meet criteria: • At least three hepatitis B vaccinations, with different dates of service. O One of the three vaccinations can be a newborn hepatitis B vaccination during the eight-day period that begins on the date of birth and ends seven days after the date of birth. For example, if the member's date of birth is December 1, the newborn hepatitis B vaccination must be on or between December 1 and December 8. • Anaphylaxis due to the hepatitis B vaccine.

Category	Description
	• History of hepatitis B illness. Varicella vaccination (VZV) Children with either of the following meet criteria: • At least one VZV vaccination, with a date of service on or between the child's first and second birthdays. • History of varicella zoster (e.g., chicken pox) illness on or before the child's second birthday. Pneumococcal Conjugate At least four pneumococcal conjugate vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. Hepatitis A Children with either of the following meet criteria: • At least one hepatitis A vaccination, with a date of service on or between the child's first and second birthdays. • History of hepatitis A illness on or before the child's second birthday. Rotavirus Children with any of the following meet criteria: • At least two doses of the two-dose rotavirus vaccine on different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • At least three doses of the three-dose rotavirus vaccine on different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • At least one dose of the two-dose rotavirus vaccine and at least two doses of the three-dose rotavirus vaccine, all on different dates of service, on or before the child's second birthday. Do not count a vaccination administered prior to 42 days after birth. • Anaphylaxis due to the rotavirus vaccine on or before the child's second birthday. Influenza At least two influenza vaccinations, with different dates of service on or before the child's second birthday. Do not count a vaccination administered prior to 6 months (180 days) after birth. • One of the two vaccinations can be an LAIV vaccination administered on the child's second birthday. Do not count an LAIV vaccination administered before the child's second birthday.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure guidance to remove the numerator criteria related to adverse reactions to vaccines, as these do not align with intent of the measure which is to ensure children receive the CDC-recommended appropriate vaccines by age 2 to prevent disease, which is more cost effective than treatment, and to protect the health of their community. We also propose to update the denominator exclusions by moving the numerator inclusion criteria for children who are immunocompromised to the denominator exclusion, as this patient population is not appropriate for assessment of the quality action. Additionally, we propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment data and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Furthermore, we propose to update the numerator to remove seropositive test results as the CDC does not specifically recommend conducting antibody testing to determine immunity to disease in lieu of vaccination.

D.40 Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	277
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea. **The measure numerator is revised to read:** Patients who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea. **Updated numerator definition: Added:** Respiratory Event Index (REI) – is a measure of respiratory events per unit of time for a home sleep apnea test. **Updated numerator note: Revised:** The quality data codes below should be used for assessment of a MIPS eligible clinician's actions within 2 months of the initial evaluation for obstructive sleep apnea. **The measure numerator options are revised to read:** **Performance Met:** Apnea hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea **Denominator Exception:** Documentation of reason(s) for not measuring an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) within 2 months of initial evaluation for suspected obstructive sleep apnea (e.g., medical, neurological, or psychiatric disease that prohibits successful completion of a sleep study, patients for whom a sleep study would present a bigger risk than benefit or would pose an undue burden, dementia, patients who decline AHI/RDI/REI measurement, patients who had a financial reason for not completing testing, test was ordered but not completed, patients decline because their insurance (payer) does not cover the expense)) **Performance Not Met:** Apnea hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) not documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea, reason not given
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description and numerator options language to harmonize the description with the revised numerator language. We propose to revise the numerator to add a respiratory event index (REI) assessment and a 2-month timeframe within which a sleep study would be performed to determine the severity of suspected obstructive sleep apnea as the REI is appropriate for determining sleep apnea severity and the extended time frame will allow the clinicians flexibility in clinical workflow. We propose to update the numerator definition to include a definition of REI to provide clarity and consistency. We also propose to update the numerator note to provide further guidance on meeting numerator compliance. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.41 Rehabilitative Therapy Referral for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.
Substantive Change:	**Updated denominator criteria: Removed:** coding for Physical and Occupational Therapy and Speech Language Pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove coding for Physical and Occupational Therapy and Speech Language Pathology from the denominator eligible encounters. While these clinicians may treat patients with Parkinson's disease, the required quality actions cannot be feasibly implemented for these clinician types as it requires a referral.

D.42 Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	305
CMS eCQM ID:	CMS137v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation. **Updated guidance: Removed:** The new episode of alcohol and other drug dependence should be the first episode of the measurement period that is not preceded in the 60 days prior by another episode of alcohol or other drug dependence. **The measure stratification is revised to read:** Report a total score, and each of the following strata: Stratum 1: Patients age 13-17 at the start of the measurement period Stratum 2: Patients age 18-64 at the start of the measurement period Stratum 3: Patients age 65 and older at the start of the measurement period **The measure initial patient population is revised to read:** Patients age 13 years of age and older as of the start of the measurement period who were diagnosed with a new SUD episode during a visit between January 1 and November 14 of the measurement period. **The denominator exclusions are revised to read: Removed**: Exclude patients with a negative diagnosis history, defined as an encounter or medication treatment for a diagnosis of alcohol, opioid or other drug abuse or dependence in the 60 days prior to the first episode of alcohol or drug dependence. **The measure definition is revised to read:** The new SUD episode is the first encounter during the Intake Period with a diagnosis of SUD with no encounter or medication treatment for a diagnosis of SUD in the 60 days prior. The initiation of treatment is the first SUD treatment within 14 days of a new SUD episode. Treatment includes inpatient SUD admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations, and medications for the treatment of SUD. The Intake Period: January 1-November 14 of the measurement year. The Intake Period is used to capture new SUD episodes. The November 14 cut-off date ensures that all services can occur before the measurement period ends. **Updated logic and logic definitions: Removed:** emergency department visits and medically managed withdrawals from the negative lookback rules. **Revised:** to account for instances when there are multiple qualifying initiation events. **Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read:** Numerator 1: Initiation of treatment includes either an intervention or medication for the treatment of SUD within 14 days of the new SUD episode Numerator 2: Engagement in ongoing SUD treatment within 34 days of initiation includes: 1. A long-acting SUD medication on the day after the initiation through 34 days after the initiation of treatment 2. One of the following options on the day after the initiation of treatment through 34 days after the initiation of treatment: a) two engagement visits, b) two engagement medication treatment events, c) one engagement visit and one engagement medication treatment event
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description, initial patient population, numerator, denominator exclusions, and definition to remove any reference to 'substance abuse' with the measure as the terms "abuse and dependence" have been replaced by 'substance use disorder (SUD)' in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5). This would align terminology within the measure to current clinical terminology. We propose to update the measure guidance and definition to clarify what defines an episode of SUD and update the stratification from 2 age groups to 3 age groups. We propose to update the measure logic and logic definitions to remove emergency department visits and medically managed withdrawals from the negative lookback rules to align with the measure intent since the emergency department may not represent the best setting for the initiation of SUD treatment and the measure would not be applicable for patients already receiving SUD therapy. We also propose an additional revision to the measure logic and logic definitions to specify how data should be handled when there are multiple qualifying initiation events to ensure data collection accuracy. Additionally, we propose to update the

Category	Description
	logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.43 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years
Substantive Change:	**Updated guidance: Removed:** Patient self-report for procedures as well as diagnostic studies should be recorded in 'Procedure, Performed' template or 'Diagnostic Study, Performed' template in QRDA-1. **The measure initial patient population is revised to read:** Women 24-64 years of age by the end of the measurement period with a visit during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure guidance to remove statements related to QRDA-1 as we publish separate QRDA implementation guides. We also propose to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it would align with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.44 Chlamydia Screening for Women

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	310
CMS eCQM ID:	CMS153v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**The measure stratification is revised to read:** Stratum 1: Patients age 16-20 by the end of the measurement period Stratum 2: Patients age 21-24 by the end of the measurement period. **The measure initial patient population is revised to read:** Women 16 to 24 years of age by the end of the measurement period who are sexually active and who had a visit in the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure stratification and initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it would align with HEDIS measure requirements and creates consistency for implementation across programs. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.45 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure there are values captured for both diastolic and systolic blood pressure when evaluating criteria. And to avoid blood pressure values falling into multiple categories. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type we propose to revise the logic for the second hypertensive blood pressure reading (systolic blood pressure (SBP) 130-139 or diastolic blood pressure (DBP) 80-89) to avoid blood pressure values falling into multiple categories and to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.

D.46 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v11
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**The measure initial patient population is revised to read:** Patients aged 65 years and older at the start of the measurement period with a visit during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated value set/coding: Added:** coding for physical and occupational therapy.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it would align with HEDIS measure requirements and creates consistency for implementation across programs. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Additionally, we propose to add occupational and physical therapy evaluation visits as applicable encounters as these clinicians interact with older adults that may be more susceptible to falls. Occupational therapists are "uniquely qualified to address the multifactorial nature of falls, given their knowledge of factors that influence occupational performance."[1] There is a strong body of evidence that supports the role of physical therapists in reducing fall risk and fall prevention as outlined within the American Physical Therapy Association (APTA) handout: https://www.apta.org/patient-care/public-health-population-care/balance-and-falls/research-on-falls#.

[1] Peterson, E. W., & Clemson, L. (2008). Understanding the role of occupational therapy in fall prevention for community-dwelling older adults. OT Practice, 13(3), CE1–CE8. https://www.researchgate.net/publication/286974169_Understanding_the_role_of_occupational_therapy_in_fall_prevention_for_community-dwelling_older_adults.

D.47 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
NQF # / eCQM NQF #:	0658 / N/A
Quality#:	320
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. **The measure denominator is revised to read: For all collection types:** All patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy. **Updated denominator criteria: For all collection types: Revised:** Patients aged 45 to 75 on date of encounter.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description, denominator, and denominator criteria for all collection types to expand the denominator eligible patient population to reflect USPSTF guidance that screening colonoscopies begin at age 45.

D.48 CAHPS for MIPS Clinician/Group Survey

Category	Description
NQF # / eCQM NQF #:	0005 / N/A
Quality#:	321
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	CMS-approved Survey Vendor
Current Measure Description:	The Consumer Assessment of IHealthcare Providers and Systems (CAIIPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)
Substantive Change:	**Updated case-mix adjustor: Removed:** Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey item specific to the case-mix adjustor for "Asian language survey completion". **Added:** language other than English spoken at home.
Measure Steward:	Agency for Healthcare Research & Quality
High Priority Measure:	Yes
Measure Type:	Patient Engagement/Experience
Rationale:	We propose to update the case-mix adjustor as only a small percentage of patients who report speaking a language other than English at home actually complete the survey in that language. By capturing the language that is actually spoken within the patient's home, we believe this will more accurately capture their language preference. For more information please refer to section IV.A.10.c.(1)(b)(ii)(A) of this proposed rule.

D.49 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator exception: Revised:** Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (e.g., present or planned atrial appendage occlusion or ligation).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exception by revising the language to account for the removal of patients that do not get prescribed an FDA-approved anticoagulant based on medical reason(s) from the performance rate as prescribing medication may not be appropriate in the instance a patient has or may undergo an atrial appendage occlusion or ligation. This procedure would eliminate the patient's need to take oral anticoagulation (OAC) therapy as left atrial appendage occlusion (LAAO) has shown similar efficacy to OAC on stroke rate (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7189129/#).

D.50 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	366
CMS eCQM ID:	CMS136v12
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated definition: Revised:** Index Prescription Start Date (IPSD): The earliest prescription dispensing date for an ADHD medication where the date is in the Intake Period and an ADHD medication was not dispensed during the 120 days prior. Continuation and Maintenance Phase: The 300 days following the IPSD. **The measure initial patient population is revised to read:** Initial Population 1: Children 6-12 years of age as of the Intake Period who were prescribed an ADHD medication during the Intake Period and who had a visit during the measurement period. Children are removed if they were actively on ADIID medication in the 120 days prior to the IPSD, or had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Initiation Phase. Initial Population 2: Children 6-12 years of age as of the Intake Period who were prescribed an ADHD medication during the Intake Period and remained on the medication for at least 210 days during the 301-day period, beginning on the IPSD through 300 days after the IPSD, and who had a visit during the measurement period. Children are removed if they were actively on ADHD medication in the 120 days prior to the IPSD, or had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Continuation and Maintenance Phase. **The measure denominator exclusion is revised to read:** Exclude patients diagnosed with narcolepsy at any point in their history or during the measurement period. Exclude patients who are in hospice care for any part of the measurement period. **The measure numerator is revised to read:** Numerator 1: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase. Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits during the 31-300 days after the IPSD. **Updated logic and logic definitions: Revised:** For Numerator 2: logic to allow for only one of the two qualifying follow up visits to be an online assessment visit. **Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure to extend the intake period to 12-months to allow for the assessment to follow-up for patients newly prescribed ADHD medications to occur at any time during the year. We propose to align the definitions with the 12-month intake period as well as adding clarity to the definitions. We propose to revise the denominator exclusions, repositioning criteria listed within the denominator exclusion to the initial patient population to streamline measure logic. Additionally, we propose to revise the initial patient population to align with definitions and to revise the anchor for age calculation to be based off of the intake period, as this is when patients can start taking ADHD medication. We propose to revise the logic and logic definitions for numerator two to ensure that only one of the two qualifying follow up visits be an online assessment for numerator compliance. We believe this revision would align with current clinical care which may not occur as an in-office visit. We propose to update logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.51 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1: Patients who died any time prior to the end of the measure assessment period. 2: Patients who received hospice or palliative care services between the start of the denominator period and the end of the measurement assessment period. 3: Patients who were permanent nursing home residents between the start of the denominator period and the end of the measurement assessment period. 4: Patients with a diagnosis of bipolar disorder any time prior to the end of the measure assessment period. 5: Patients with a diagnosis of personality disorder emotionally labile any time prior to the end of the measure assessment period. 6: Patients with a diagnosis of schizophrenia or psychotic disorder any time prior to the end of the measure assessment period. 7: Patients with a diagnosis of pervasive developmental disorder any time prior to the end of the measure assessment period. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Added:** coding for preventive medicine encounters. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Adolescent patients 12 to 17 years of age and adult patients 18 years of age and older who achieved remission at 12 months as demonstrated by the most recent 12 month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding to "Contact or Office Visit" value set for preventive encounters.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the denominator exclusion statements for the eCQM Specifications collection type by adding relevant interval periods to clarify timing associated with each denominator exclusion in the logic. We also propose to revise the numerator statement to provide clarity around the measure's intent to evaluate the most recent PHQ-9 or PHQ-9M assessment and to align with measure logic, which better expressed our intent. The intent of the measure is to facilitate improved response and remission scores through appropriate and effective treatment for patients diagnosed with depression. Additionally, we propose to update the value set/coding for the denominator criteria for all collection types to include preventive medicine encounters to engage patients and assess remission of depression.

D.52 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v11
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Revised:** Only the first referral made between January 1 – October 31 of the measurement period will be considered for this measure to allow adequate time for the referring clinician to collect the consult report by the end of the measurement period. **Revised:** The consultant report that will successfully close the referral loop should be related to the first referral for a patient during the measurement period. If there are multiple consultant reports received by the referring clinician which pertain to a particular referral, use the first consultant report to satisfy the measure. Eligible clinicians reporting on this measure should note that all data for the reporting year is to be submitted by the deadline established by CMS. Therefore, eligible clinicians who refer patients towards the end of the reporting period (i.e., October), should request that clinicians to whom they referred their patients share their consult reports as soon as possible in order for those patients to be counted in the measure numerator during the measurement period. When clinicians to whom patients are referred communicate the consult report as soon as possible with the referring clinician, it ensures that the communication loop is closed in a timely manner and that the data are included in the submission to CMS. **The measure instructions are revised to read: For the MIPS CQMs Specifications collection type:** This measure is to be submitted a minimum of once per performance period for the first referral for all patients during the measurement period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure for the patients for whom a referral was made during the measurement period based on the services provided and the measure-specific denominator coding. The clinician who refers the patient to another clinician is the clinician who should be held accountable for the performance of this measure. All MIPS eligible clinicians reporting on this measure should note that all data for the reporting year is to be submitted by the deadline established by CMS, however, only first referrals made between January 1 – October 31 (the measurement period) will count towards the denominator to allow adequate time for the referring clinician to collect the consult report by the end of the performance period. When clinicians to whom patients are referred communicate the consult report as soon as possible with the referring clinicians, it ensures that the communication loop is closed in a timely manner and that the data is included in the submission to CMS. **Updated initial patient population: For the eCQM Specifications collection type: Revised:** Number of patients, regardless of age, who had an encounter during the measurement period and the first referral occurred by one clinician to another clinician on or before October 31. **The measure denominator is revised to read: For the MIPS CQMs Specifications collection type:** Number of patients, regardless of age, who had an encounter during the performance period and were referred by one clinician to another clinician on or before October 31. **The measure numerator is revised to read: For all collection types:** Number of patients with a referral on or before October 31, for which the referring clinician received a report from the clinician to whom the patient was referred.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise multiple components of the measure, across all collection types, to allow for a 2-month period to close the referral loop in alignment with interested parties' feedback and published literature. This revision would allow adequate time for the referring clinician to collect the consult report prior to the end of the performance period. Additionally, we propose to shorten the timeframe to determine denominator eligibility to account for the extension in timeframe for numerator compliance. We propose to add language to multiple components of the measure for all collection types to clarify that only the first referral should be utilized for denominator eligibility.

D.53 Functional Status Assessment for Total Hip Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	376
CMS eCQM ID:	CMS56v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery. **Updated denominator exclusion: Revised:** 1. Exclude patients with two or more fractures indicating trauma in the 24 hours before or at the start of the total hip arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description to clarify the logic associated with the age requirement, as described above in the revised measure description. We propose to revise the denominator exclusion so the timing of the lower body fracture in relation to the THA is clearly reflected. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.54 Functional Status Assessments for Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v12
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update logic and logic definitions related to hospice care to add flexibility to how data may be captured or stored to allow for different workflows and systems and more closely align with exclusion criteria, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.55 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist. **The measure initial patient population is revised to read:** Children, 6 months – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the measure description and initial patient population to add context and clarify that the measure is to be reported by dentists. We propose to revise the age criteria in the initial patient population logic to clarify the measure's intent to include patients that are 20 years of age at the start of the measurement period, to ensure the appropriate patient population is being assessed for tooth decay or cavities. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population.

D.56 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v12
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months 20 years of age, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months – 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist **Updated guidance: Added:** Telehealth encounters are not eligible for this measure because the measure does not contain telehealth-eligible codes and requires a clinical action that cannot be conducted via telehealth. **The measure stratification is revised to read:** Population 1: Patients age 6 months – 5 years at the start of the Measurement Period Population 2: Patients age 6-12 years at the start of the Measurement Period Population 3: Patients age 13-20 years at the start of the Measurement Period **The measure initial patient population is revised to read:** Children, 6 months 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated logic and logic definitions: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **Updated value set/coding: Removed:** value sets for Preventive Care, Telephone Visits, Online Assessments, and Office Visits.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and initial patient population to capture patients who are 20 years old at the start of the measurement period, which would align with the measure narrative and intent of being reported by a dentist. We propose to clarify that telehealth encounters are not eligible. We propose to make further revisions to the guidance and initial patient population based on USPSTF recommendations and reimbursement practices that primary care providers are unlikely to perform the clinical action of providing a fluoride varnish, therefore the measure intent, as described in the revised measure description, is for dentists to report this measure. We propose to update the stratification to provide clarity on the age anchor timing and align with measure intent and incorporate the recommended format into the stratification logic. We also propose to update the logic and logic definitions related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion criteria more closely, ensuring those patients not appropriate for the assessment of the quality action are removed from the denominator eligible patient population. Additionally, we propose to remove value set/coding for preventive medicine encounters, telephone visits and online assessments.

D.57 Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.
Substantive Change:	**Updated denominator exclusion: Removed:** 1. Meningococcal, Tdap and/or HPV vaccine contraindicated OR patient allergic to the meningococcal, Tdap, and/or HPV vaccine. 2. Encephalopathy due to Tdap vaccine. **Updated numerator options: Added:** denominator exception option for each submission criteria to reflect patients who had anaphylaxis due to the vaccine(s) being assessed. **Added:** For Submission Criteria 2: denominator exception option for patients who had encephalitis due to the tetanus, diphtheria or pertussis vaccine. **Updated numerator: Revised:** For Submission Criteria 3: Adolescents who completed the HPV vaccine series on or between the patient's 9th and 13th birthdays.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the denominator exclusions for anaphylaxis and encephalopathy as patients associated with these clinical conditions should still be assessed for administration of the meningococcal, Tdap and/or HPV vaccines. We propose to revise the numerator options to add additional parameters for denominator exceptions for those patient populations that would not be appropriate for the clinical quality action of vaccine administration. We also propose to update the numerator for Submission Criteria 3 to require completion of the HPV vaccine series on or between the 9th and 13th birthday to align with the measure's intent as described in the current measure description which is to ultimately improve adolescent immunization rates and prevent disease which is more cost effective than treatment of the disease.

D.58 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications collection type.
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type for this measure due to an insufficient volume of data as indicated in the 2022 Quality Benchmarks. The current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/608/2022%20Quality%20Benchmarks.zip. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.

D.59 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator note: For** the **MIPS CQMs Specifications collection type: Revised:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the language for the denominator note for the MIPS CQMs Specifications collection type to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.

D.60 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
NQF # / eCQM NQF #:	2152 / N/A
Quality#:	431
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**Updated denominator exclusion: Added: For all submission criteria:** 1. Patients with dementia any time during the patient's history through the end of the measurement period. 2. Patients who use hospice services any time during the measurement period. **Updated denominator criteria: Added:** coding for audiology. **Updated numerator definition: Revised: For Submission Criteria 1:** AUDIT Screening Instrument (score > 8) **Updated numerator options: Removed: For all submission criteria:** all denominator exceptions.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure to add denominator exclusions and remove denominator exceptions to reduce burden by removing patients from the denominator eligible patient population as the clinical quality action may not be appropriate. This revision would allow clinicians to identify the measure's intended patient population prior to numerator compliance being determined, which would reduce the denominator patient population applicable for reporting. Additionally, we propose to revise the AUDIT screening instrument score as this would align with the World Health Organization (WHO) guidelines. We also propose to update the denominator criteria to include coding for audiology as this measure is applicable to their scope of care. Studies have shown a positive correlation between hearing loss and alcohol consumption, more markedly with heavy alcohol consumption, making this concept important for audiologists to assess (https://academicworks.cuny.edu/cgi/viewcontent.cgi?article=5338&context=gc_etds).

D.61 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated guidance: For the eCQM Specifications collection type: Revised:** Initial Population 1: All patients who have an active diagnosis of clinical ASCVD anytime during the measurement period or ever had an ASCVD procedure. **Added:** Millimoles per liter (mmol/L) should be converted to milligrams per deciliter (mg/dL) for reporting this measure. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Population 1: All patients who have an active diagnosis of clinical ASCVD or ever had an ASCVD procedure. **Updated denominator exclusion: For all collection types: Removed: For all submission criteria:** Patients who have a diagnosis of pregnancy at any time during the measurement period. **Updated definition: For the MIPS CQMs Specifications collection type: Added:** Ezetimibe / Rosuvastatin – Roszet – Fixed Dose Combination' to Table 1 Statin Medication Therapy List. **Revised:** Lipoprotein Density Cholesterol (LDL-C) result – A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. **Updated denominator exception: For the eCQM Specifications collection type: Added:** Patients with documentation of a medical reason for not being prescribed statin therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure, for the eCQM Specifications collection type, to revise the timing associated with a clinical ASCVD diagnosis to align with the measure intent of only including patients with an active diagnosis. We also propose to remove the pregnancy exclusion for all collection types to align with U.S Food and Drug Administration (FDA) recommendations that pregnancy be removed as a contraindication in prescribing statins (https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol). We propose to revise the eCQM Specifications collection type in order to standardize the method that represents the lab value for low-density lipoprotein cholesterol (LDL-C). We propose to revise the measure to request that Millimoles per liter (mmol/L) should be converted to milligrams per deciliter (mg/dL).We also propose to update the definitions for the MIPS CQMs Specification collection type by adding another medication to the statin medication therapy list for completeness and to clarify which test results should be used for both direct and calculated test results for fasting or non-fasting LDL-C test if they happen to be available on the same day. We propose to update the denominator exceptions for the eCQM Specification collection type by adding a medical reason for not being prescribed statin therapy to align with American College of Cardiology/American Heart Association (ACC/AHA) guidelines (https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2019/03/07/16/00/2019-acc-aha-guideline-on-primary-prevention-gl-prevention).

D.62 Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	440
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**Updated denominator note: Removed:** denominator note. **Updated denominator exception: Added:** Pathology report for tissue specimens produced from wide local excisions or re-excisions.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the denominator note and add a denominator exception to simplify identifying the denominator eligible patient population and better address cases of excisions and re-excisions that may be included via the pathology CPT codes 88304 & 88305.

D.63 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	441
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated
Substantive Change:	**The measure numerator note is revised to read:** For Component 1: • Submit G9789 for blood pressures recorded during Inpatient Stays, Emergency Room Visits, or Urgent Care Visits. In order to meet performance, the most recent blood pressure should be recorded within the performance period. • Home BP results which can be obtained digitally, in writing or verbally, and are able to be stored in the EMR in a discrete field can be included. Accepting these BP results is at the discretion of the provider. **Updated denominator exception: Revised:** For Component 1: Blood pressure recorded during inpatient stays, Emergency Room Visits, or Urgent Care Visits
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to revise the numerator note to capture additional blood pressure results as a response to the impact COVID-19 has had on the availability of in-office blood pressure results. Additionally, we propose to revise the denominator exception with the removal of self-reported blood pressure results. This revision allows clinicians to utilize patient reported blood pressures, documented in the electronic medical record, for the determination of numerator compliance.

D.64 Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.
Substantive Change:	**The measure title is revised from 'Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)' to:** Percentage of Patients who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) **The measure description is revised to read:** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life. **The measure numerator is revised to read:** Patients who received systemic cancer-directed therapy in the last 14 days of life. **Updated numerator note: Added:** Definition of systemic cancer-directed therapy includes: • All traditional cytotoxic chemotherapy (such as alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, and antitumor antibiotics); • Immunotherapy; • Biologics (such as Herceptin, Rituxan); and • Targeted agents Do not include supportive care therapies (e.g., growth factors, bisphosphonates, RANK ligand inhibitors, nausea medications or fluids if these are not given in association with "systemic cancer-directed therapy"). Hormonal therapies and steroids are not included in this systemic cancer directed therapy definition. **The measure numerator options are revised to read:** **Performance Met:** Patient received systemic cancer-directed therapy in the last 14 days of life. **Performance Not Met:** Patient did not receive systemic cancer-directed therapy in the last 14 days of life.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise multiple components of the measure to reflect the measure intent to only include systemic cancer-directed therapy for the purposes of this measure. We propose to clarify the terminology and revise the numerator note to include a definition for systemic cancer-directed therapy to allow for precise implementation of the measure. This ensures that the denominator eligible patient population aligns with the treatments that have been shown to not only negatively impact the patient's experience at the end of life, but also have not been shown to improve outcomes (https://ascopubs.org/doi/full/10.1200/JCO.2016.70.1474). ASCO advocates that "curtailing unnecessary treatments at the end of life will help drive down end-of-life resource utilization costs" and that "early integration of palliative care/hospice services for patients with late stage cancer in order to avoid aggressive measures at the end-of-life."

D.65 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Back Pain After Lumbar Discectomy/Laminectomy' to:** Back Pain After Lumbar Surgery **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion and numeric pain scale. **Updated denominator: Revised:** DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The 12-month period in which eligible patients have a procedure. This allows for enough time for a follow-up assessment to occur during the performance period. The "denominator identification period" includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Revised:** NUMERATOR (Submission Criteria 1): All eligible patients whose back pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS or Numeric Pain scale at three months (6 to 20 weeks) postoperatively. **Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose back pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Updated numerator definition: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance and allow for telephone screenings. **Added:** For Submission Criteria 1: Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (e.g., phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that is in which a postoperative VAS or Numeric pain scale score is obtained. Preoperative Assessment VAS or Numeric Pain – A preoperative VAS or Numeric pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS or Numeric score was obtained, use the VAS or Numeric score that is the most recent and prior to the procedure. Postoperative Assessment VAS or Numeric Pain – A postoperative VAS or Numeric pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS or Numeric score was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.

Category	Description
	Visual Analog Scale (VAS) – A "visual analog scale" is a continuous line indicating the continuum between two states of being. A copy of the tool can be obtained below or at the following link Visual Analog Scale Tool. Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (e.g., phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. Back Pain Target #2 – A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement in back pain is greater than or equal to 5.0 points. **Updated numerator note: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance, replace 'change' with 'improvement', and updated to allow for telephone screenings. **Added:** For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 or G2139 is submitted. • VAS Pain or Numeric Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool • Postop VAS or Numeric Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS or Numeric value is greater than 3.0 and no valid preop to measure improvement • Postoperative VAS or Numeric value is greater than 3.0 and preoperative VAS or Numeric Pain Scale (to measure improvement) is administered beyond the 3-month timeframe prior to and including the date of procedure (e.g., 6 months before procedure) **Updated numerator options: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance. **Added:** For Submission Criteria 2: **Performance Met:** Back pain as measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater. **Performance Not Met:** Back pain was not measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Performance Not Met:** Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was greater than 3.0 AND Back pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated less than an Improvement of 5.0 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise this measure to expand the eligible procedures to include lumbar fusion, to capture a more complete patient population for lumbar surgery. This would be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision would be reflected within multiple components within the specification. Additionally, we propose to add the Numeric Pain scale as an option for numerator compliance. Inclusion of this tool would allow flexibility by allowing virtual visits for completion of the assessment. We propose to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We are also proposing to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we propose to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions would align with the measure intent and combining of two lumbar procedures as stated in the revised measure description. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.66 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Leg Pain After Lumbar Discectomy/ Laminectomy' to:** Leg Pain After Lumbar Surgery **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion and numeric pain scale. **Updated denominator: Revised**: DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The 12- month period in which eligible patients have a procedure. This allows for enough time for a follow-up assessment to occur during the performance period. The "denominator identification period" includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Revised:** NUMERATOR (Submission Criteria 1): All eligible patients whose leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS or Numeric Pain scale at three months (6 to 20 weeks) postoperatively. **Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) or Numeric Pain scale at one year (9 to 15 months) postoperatively. **Updated numerator definition: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance and allow for telephone screenings. **Added:** For Submission Criteria 1: Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (e.g., phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that is in which a postoperative VAS or Numeric pain scale score is obtained. Preoperative Assessment VAS or Numeric Pain – A preoperative VAS or Numeric pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS or Numeric score was obtained, use the VAS or Numeric score that is the most recent and prior to the procedure. Postoperative Assessment or Numeric VAS Pain – A postoperative VAS or Numeric pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS or Numeric score was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.

Category	Description
	Visual Analog Scale (VAS) – A "visual analog scale" is a continuous line indicating the continuum between two states of being. A copy of the tool can be obtained below and at the following link Visual Analog Scale Tool. Numeric Pain Scale- a numeric pain scale is one that asks the patient to rate their pain on a scale of 0 to 10 where zero is "No Pain" and 10 is pain that is intolerable. This type of pain score tool can be administered verbally to the patient and because it does not involve a visual line, multiple modes of administration (e.g., phone, virtual visit, patient portal, verbally in-person, etc.) are acceptable. Leg Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their leg pain as less than or equal to 3.0. Leg Pain Target #2 – A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively one year (9 to 15 months) after the procedure AND the improvement in leg pain is greater than or equal to 5.0 points. **Updated numerator note: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance, replace 'change' with 'improvement', and updated to allow for telephone screening. **Added:** For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1052 or G2147 is submitted. • VAS Pain or Numeric Scale is not administered postoperatively at one year (9 to 15 months) • Leg pain is measured using a different patient reported functional pain tool • Postoperative VAS or Numeric Pain scale is administered less than 9 months or greater than 15 months (1 year window) • Postoperative VAS or Numeric value is greater than 3.0 and no valid preoperative VAS Pain scale to measure improvement • Postoperative VAS or Numeric value is greater than 3.0 and preoperative VAS or Numeric Pain scale (to measure improvement) is administered beyond the 3-month timeframe prior to and including the date of procedure (e.g., 6 months before procedure) **Updated numerator options: Revised:** For Submission Criteria 1: to reflect inclusion of Numeric Pain scale for numerator compliance. **Added:** For Submission Criteria 2: **Performance Met:** Leg pain as measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater. **Performance Not Met:** Leg pain was not measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively. **Performance Not Met:** Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale at one year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) or Numeric pain scale within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise this measure to expand the eligible procedures to include lumbar fusion, in order to capture a more complete patient population for lumbar surgery. This would be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision would be reflected within multiple components within the specification. Additionally, we propose to add the Numeric Pain scale as an option for numerator compliance. Inclusion of this tool would allow flexibility by allowing virtual visits for completion of the assessment. We propose to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We are also proposing to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we propose to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions would align with the measure intent and combining of two lumbar procedures. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.67 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated denominator exception: Revised:** Patient refused the bone density evaluation at the time ordered or did not have it performed within 3 months after the start of ADT.
Measure Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exception to align with the measure logic and intent of receiving an initial bone density evaluation prior to the start or within 3 months of ADT.

D.68 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**The measure denominator definition is revised to read:** Risk factors for POV – • Surgery ≥ 30 minutes • Age ≥ 3 years • Strabismus surgery • History of POV or Post-Operative Nausea and Vomiting (PONV)/motion sickness in patient • Family History of POV/PONV • Post-pubertal female • Adenotonsillectomy • Otoplasty • Anticholinesterases • Long-acting opioids
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure denominator definition to reflect the 2020 clinical guidance for the management of postoperative nausea and vomiting.

D.69 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure title is revised from 'Functional Status After Lumbar Discectomy/Laminectomy' to:** Functional Status After Lumbar Surgery **The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure. **Updated instructions: Revised:** to include lumbar fusion. **Updated denominator: Revised:** DENOMINATOR (SUBMISSION CRITERIA 1): Patients 18 years of age or older as of January 1 of the denominator identification period who had a lumbar discectomy/laminectomy procedure performed during the denominator identification period. **Added:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period. **Updated denominator criteria: Added:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years by October 1 of the Denominator Identification Period Patient procedure during the Denominator Identification Period – lumbar fusion **Updated denominator exclusion: Removed:** For Submission Criteria 1: Patient had any additional spine procedures performed on the same date as the lumbar discectomy/laminectomy. **Added:** For Submission Criteria 1: Patient had a lumbar fusion on the same date as the discectomy/ laminectomy procedure. For Submission Criteria 2: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis. **Updated denominator definition: Added:** For Submission Criteria 2: Denominator Identification Period – The twelve month period in which eligible patients have a denominator eligible procedure. This allows for enough time for a follow-up assessment to occur during the twelve month performance period. The denominator identification period includes dates of procedure 10/1/2021 to 9/30/2022. **Updated numerator: Added:** NUMERATOR (Submission Criteria 2): All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI Version 2.1a) patient reported outcome tool at one year (9 to 15 months) postoperatively. **Updated numerator definition: Added:** For Submission Criteria 2: Measure Assessment Period (Performance Period) – The period of time following the procedure date that a postoperative Oswestry Disability Index (ODI version 2.1a) functional status score can be obtained. Preoperative Assessment Oswestry Disability Index (ODI version 2.1a)- A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) – A postoperative ODI functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to nine months and after fifteen months postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Oswestry Disability Index (ODI version 2.1a) Patient Reported Outcome Tool An ODI patient reported outcome tool (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools. A copy of the tool can be obtained below or at the following link: https://eprovide.mapi-trust.org/instruments/oswestry-disability-index. Functional Status Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 – A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement is demonstrated as a decrease in ODI score by greater than or equal to 30 points.

Category	Description
	Updated numerator note: Added: For Submission Criteria 2: It is recommended that both a preoperative and postoperative assessment tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 or G2143 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI is greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (e.g., 6 months before procedure.) **Updated numerator options: Added:** For Submission Criteria 2: **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of less than 30 points.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise this measure to expand the eligible procedures to include lumbar fusion, in order to capture a more complete patient population for lumbar surgery. This would be accomplished by stratifying the measure to create a submission criterion for lumbar discectomy/laminectomy procedures and a submission criterion for lumbar fusion. This revision would be reflected within multiple components within the specification. We propose to update the denominator to reflect the stratified procedure types by renaming the original denominator to Denominator (Submission Criteria 1). We are also proposing to revise the Submission Criteria 1 exclusion to remove patients who had additional spine procedures on the same date and add patients who had a lumbar fusion on the same date. Additionally, we propose to add patients who had cancer, acute fracture or infection related to the lumbar spine to the denominator exclusions. These proposed revisions would align with the measure intent and combining of two lumbar procedures. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.70 Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A / 3475e
Quality#:	472
CMS eCQM ID:	CMS249v5
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Substantive Change:	**Updated guidance: Revised:** Patients are excluded from the measure if they have one or more risk factors for osteoporosis, including a result indicating that the patient should be considered for bone density testing on one of the following risk assessment instruments: • 10-year probability of major osteoporotic fracture of 8.4 percent or higher as determined by the FRAX • ORAI score of >=9 • OSIRIS score of <1 • OST score of <2" **The measure initial patient population is revised to read:** Female patients ages 50 to 63 years at the start of the measurement period with an encounter during the measurement period. **The measure denominator exclusion is revised to read:** 1. Exclude patients with one of the following risk factors. 2. Risk factors are grouped by when they occur in relation to the measurement period. 3. The following risk factors must be active during the measurement period: BMI <= 20 kg/m2 (must be the first BMI of the measurement period) Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) 4. The following risk factors may occur at any time in the patient's history prior to the start of the measurement period: Osteoporosis Osteopenia 5. The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: Gastric bypass Aromatase inhibitors Documentation of history of hip fracture in parent 6. The following risk factors may occur at any time in the patient's history or during the measurement period: Glucocorticoids [cumulative medication duration >= 90 days] Osteoporotic fracture Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic malnutrition Chronic liver disease Rheumatoid arthritis Hyperthyroidism Type I Diabetes End stage renal disease Osteogenesis imperfecta Ankylosing spondylitis Psoriatic arthritis Ehlers-Danlos syndrome Cushing's syndrome Hyperparathyroidism Marfan syndrome Lupus Chemotherapy Multiple myeloma Premature menopause Double or bilateral oophorectomy Eating disorder Amenorrhea Organ transplant" **The measure definition is revised to read:** The measure allows for clinicians to use 4 tools to assess osteoporosis or osteoporotic fracture risk. 1. The Fracture Risk Assessment Tool (FRAX[R]) is used to calculate 10-year absolute fracture risk. The FRAX evaluates a patient's 10-year probability of hip fracture and major osteoporotic fracture (clinical spine, forearm, hip, or shoulder fracture). It is applicable to people aged 40-90 years. 2. The Osteoporosis Risk Assessment Instrument (ORAI) is used to calculate osteoporosis risk. It is applicable to women >=45 years. 3. The Osteoporosis Index of Risk (OSIRIS) is used to calculate osteoporosis risk. It is applicable to patients of any age. 4. The Osteoporosis Self-Assessment Tool (OST) is used to calculate osteoporosis risk. It is applicable to patients of any age." **Updated logic and logic definitions: Revised:** the glucocorticoid active medication duration to calculate number of calendar days covered.

Category	Description
	Updated numerator exclusion: Added: Exclude patients with a result on one of the following tools, which indicates the patient should be considered for bone density testing, anytime in the patient's history prior to the time of the first DXA scan during the measurement period: FRAX[R] ten-year probability of all major osteoporosis related fracture >= 8.4 percent ORAI score of >=9 OSIRIS score of <1 OST score of <2
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure guidance to remove 'combination risk factors' and add 3 additional risk assessment tools to align with USPSTF recommendations (https://www.uspreventiveservicestaskforce.org/Home/GetFileByID/3427). Additionally, we propose to reflect the addition of the 3 risk assessment tools within the measure definition and numerator exclusions through revision of the measure. We propose to revise the initial patient population to change the time anchor from the start of the measurement period to the end of the measurement period so that it aligns with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we propose to revise the denominator exclusion to align exclusion timing of osteoporosis with the timing of osteopenia, so the same exclusion criteria would be applied to both within the narrative and logic. We propose to update the measure logic and logic definitions to evaluate the number of calendar days active on glucocorticoids to align the cumulative medication duration logic with the intent of the measure to identify patients appropriate for denominator exclusion.

D.71 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v4
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**Updated denominator exclusion: Revised:** Patients with a diagnosis of morbid obesity, or with a BMI Exam >=40 before the follow up urinary symptom score. **Updated value set/coding: For the eCQM Specifications collection type: Added:** encounter class attribute for non-telehealth eligible encounters.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the denominator exclusions to include a body mass index value equal to 40, which would align with the Centers for Disease Control and Prevention's (CDC) guideline for morbid obesity. We also propose to update the value set/coding to implement the 'virtual' encounter class attribute for the purposes of excluding non-telehealth eligible encounters within eCQM measure logic.

D.72 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).
Substantive Change:	**Updated denominator criteria: Added:** coding for Skilled Nursing Facilities. **Updated definition: Revised:** Initial Evaluation definition to include Skilled Nursery Facility coding. Added: Neck FS PROM score – The Neck FS PROM score may be achieved using one of three forms: the FOTO Neck FS PROM computer adaptive test the FOTO Neck FS PROM short form, or an alternative PROM score that is cross-walked to the Neck FS PROM. Computer adaptive test (CAT) is recommended to achieve best balance between reduced patient burden and score precision. At least one cross-walk form has been developed by the measure steward and meets scientific standards to successfully link a construct-equivalent PROM using advanced psychometric equating methods. For more information about the Neck FS PROM score forms and to access the components that are available free of charge for use with this MIPS quality measure [for example, patient-reported outcome measure(s), cross-walking, risk adjustment], visit Public Access to FOTO Measures. **Updated numerator definition: Revised:** Functional Status (FS) Score – This is the Neck FS PROM score as described under Instructions Definitions.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the denominator criteria to add coding for skilled nursing facilities for physiatrists who care for patients in nursing home settings. We believe this coding would provide additional opportunity for those clinicians to report this measure. We also propose to revise the definition to include Skilled Nursing Facility coding within the initial evaluation definition. Additionally, we propose to update the numerator definition 'Patient's Functional Status (FS) Score' to 'Functional Status (FS) Score' along with revising the definition for consistency and clarity. This update would promote the streamlining of this concept within the specification and promote ease of reading and better comprehension of this concept.

D.73 Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	481
CMS eCQM ID:	CMS646v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Substantive Change:	**Updated logic and logic definitions: Revised:** for the Initial Patient Population to capture patients whose first Bladder Cancer staging occurred during the measurement period.
Measure Steward:	Oregon Urology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the logic and logic definitions for the initial patient population to accurately capture the intended population, as stated in the current measure description. Only the first staging performed with the appropriate pathology should count for denominator eligibility for the purposes of this measure, and the first staging must occur in the measurement period. This change would better align with measure intent of capturing patients who received intravesical BCG within 6 months of bladder cancer staging, and more accurately anchor the administration of treatment.

TABLE Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for Partial Removal as Component Measures in Traditional MIPS and Proposed for Retention for Use in Relevant MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

As noted under Table Group CC, beginning with the CY 2023 performance period/2025 MIPS payment year and future years, we propose to maintain measures Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults for MIPS Value Pathways (MVP) development, and maintain measure Q110 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.4.c.(1) of this proposed rule. These measures have proposed substantive changes under Table Group DD and Table Group E.

Note: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table DD as follows: NQF # / eCQM NQF #.

The DD Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2023. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2023 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2024. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believe are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2023 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2023 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, would the DD table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: The CMS Web Interface collection type is no longer available in MIPS, except for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period. This collection type is therefore no longer listed in any tables under Table Group DD. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP. For further information on the Shared Savings Program and reporting through the CMS Web Interface collection type for APP reporting, see sections III.G.4.b.(9) and III.G.4.c.(1) of this proposed rule. For information on changes to measures under the CMS Web Interface collection type proposed for the CY 2023 performance period/2025 MIPS payment year and future years, see Table Group E of this proposed rule.

We request comments on these substantive changes.

DD.1 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / N/A
Quality#:	110
CMS eCQM ID:	CMS147v12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**The measure guidance is revised to read: For the eCQM Specifications collection type**: To enable reporting of this measure at the close of the measurement period, this measure will only assess the influenza season that starts on October 1 of the year prior to the measurement period and ends on March 31 of the measurement period. The subsequent influenza season (ending March of the following year) will be measured and reported in the following year. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.6. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure denominator is revised to read: For the eCQM Specifications collection type:** Equals Initial Population and seen for a visit between October 1 of the year prior to the measurement period and March 31 of the measurement period. **Updated denominator exclusion: For all collection types: Added:** denominator exclusion for patients receiving hospice any time during the measurement period. **Updated definition: For the eCQM Specifications collection type: Revised:** Previous Receipt - receipt of the current season's influenza immunization from another provider OR from same provider prior to the visit to which the measure is applied (typically, prior vaccination would include influenza vaccine given since July 1st). **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization between July 1 of the year prior to the measurement period to June 30 of the measurement period. **Updated numerator instructions: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types: Removed:** Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV). **Updated denominator exception: For the eCQM Specifications collection types: Removed:** all denominator exceptions (medical, patient, and system reasons).
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure guidance for the eCQM Specifications collection type to remove the paragraph regarding the influenza encounter value set and replace it with individual value sets grouped into a logic definition to be more transparent about applicable encounters. We also propose to revise the denominator for the eCQM Specifications collection type to align the identification of patients with visits that coincide with the flu season as referenced by the Food and Drug Administration (FDA) approved time for licensed flu vaccination administration (https://www.cdc.gov/flu/about/season/flu-season.htm). We propose to add hospice as a denominator exclusion for all collection types to align with other MIPS immunization measures. Additionally, we propose to revise the definition and numerator for the eCQM Specifications collection type to align performance of the measure with the immunization timeframe of the FDA approved time for licensed flu vaccination. Furthermore, for the eCQM Specifications collection type we propose to remove the denominator exceptions for medical/patient/system reasons since the ACIP guidelines specify only life-threatening allergic reactions to vaccination (i.e., anaphylaxis) as a contraindication to vaccination. Therefore, these updates reflect the ACIP recommendations and support vaccination of patients with an allergy after careful evaluation of the patient by the clinician. We propose to revise the numerator instructions for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types and the guidance for the eCQM Specifications collection type to remove the language for the LAIV formulation to align with current guidelines and would allow for the use of this formulation.

DD.2 Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	111
CMS eCQM ID:	CMS127v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 66 years of age and older who have received a pneumococcal vaccine. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 66 years of age and older at the start of the measurement period with a visit during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** denominator note. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for ESRD services, dialysis, patient counseling and/or risk factor reduction intervention services, preventive medicine, and home visit services. **Updated definitions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** definitions and coding for the added denominator exclusions: active chemotherapy, bone marrow transplant, and history of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks. **Updated denominator exclusions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** 1. Active chemotherapy during the measurement period. 2. Bone marrow transplant during the measurement period. 3. History of immunocompromising conditions prior to or during the measurement period. 4. Patent had anaphylaxis due to the pneumococcal vaccine any time during or before the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic related to hospice care to add flexibility to how data may be captured or stored. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Patients who received a pneumococcal vaccination on or after their 60th birthday and before the end of the measurement period. **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine on or after their 60th birthday and before the end of the measurement period... **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** to allow for receipt of any pneumococcal vaccine. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Removed:** Documentation of medical reason(s) for not administering pneumococcal vaccine (for example, adverse reaction to vaccine).
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description as this would reflect that the measure is no longer assessing for any receipt of the pneumococcal vaccination. Additionally, we propose to remove the denominator note from the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types as it no longer aligned fully with the revised timeframe for the administration of the pneumococcal vaccine. We propose to revise the initial patient population for the eCQM Specifications collection type to change the age determination from the start of the measurement period to the end of the measurement period so that it aligns with the HEDIS measure requirements and creates consistency for implementation. We propose to update the logic and logic definitions for the eCQM Specifications collection type related to hospice care to add flexibility to how assessment and encounter data may be captured or stored to allow for different workflows and systems to align with exclusion intent and criteria more closely. We also propose to revise the numerator for the eCQM Specifications collection type to remove language pertaining to patients who had an adverse reaction to vaccines from the numerator, so the quality action more accurately reflects patients who received a pneumococcal vaccination. We propose to update the denominator criteria for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to add coding to capture a more complete patient population as this patient population would be appropriate for the pneumococcal vaccination. We propose to update the denominator exclusions for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to add denominator exclusions as this patient population would not be appropriate for the pneumococcal vaccination. We propose to add definitions for these added denominator exclusions to outline the coding that would be sufficient to identify this patient population for consistency. Additionally, we propose to revise the numerator and numerator note to allow for receipt of any pneumococcal vaccine in

Category	Description
	accordance with the current ACIP guidelines (https://www.cdc.gov/vaccines/acip/recommendations.html). We propose to remove the numerator option allowing for documentation of medical reason(s) for not administering the vaccine and add a denominator exclusion for anaphylaxis from pneumococcal vaccine as this would better align with ACIP guidelines (https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm).

TABLE Group E: Previously Finalized Web Interface Quality Measures with Substantive Changes Proposed for the CY 2023 Performance Period and Future Years

The E Tables within this proposed rule provide the substantive changes proposed for the Web Interface quality measures in CY 2023. The changes that are made to the code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2023 may not be identified within the proposed rule due to the availability of these changes to the public. The 2023 CMS Web Interface Measure Coding Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believe are important to communicate to interested parties. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2023 CMS Web Interface Measure Coding Release Notes once posted to review all coding changes.

The PY 2023 eCQM collection type measures had substantive changes that could prove burdensome to collect, therefore, the Web Interface specifications will align with the 2023 MIPS CQM changes for these measures. The CMS Web Interface collection type is only available for purposes of APM entities reporting through the APP, starting with the CY 2023 performance period. The CMS Web Interface collection type remains through CY 2025 for Shared Savings Program ACOs reporting through the APP.

The tables below contain proposed changes for performance year 2023 Web Interface measure specifications to be used in the Shared Savings Program quality reporting.

E.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v10
Web Interface ID:	DM-2
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for nutrition and dietitian clinicians. **Updated guidance: Removed:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. **Revised to read**: To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to add encounter codes for nutrition and dietitian clinicians based upon interested parties' feedback, as they may provide nutrition counseling or therapy to patients to help manage diabetes. We propose to update the guidance/numerator instructions to remove "Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included" because it does not align with the intent of the measure, which is to ensure hemoglobin A1c control in all patients with any diagnosis of diabetes. This update allows the measure to align with its clinical intent, in accordance with the given diabetes diagnosis codes within the denominator criteria of the measure. We propose to revise the language for the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.

E.2 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v11
Web Interface ID:	PREV-12
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated definition: Added:** coding for manic episodes to the denominator exclusions definition for bipolar depression. **Updated measure numerator: Revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. **Updated guidance: Revised to read:** A depression screen is completed on the date of the encounter or up to 14 calendar days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of or up to two calendar days after the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. An example to illustrate the follow-up plan documentation timing: if the encounter is on a Monday from 3-4 pm (day 0) and the patient screens positive, the clinician has through anytime on Wednesday (day 2) to complete follow-up plan documentation. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. This measure requires documentation that a screening was conducted with a standardized depression screening tool. It is recommended that **both** a score and clinician interpretation of the score is documented, especially when a patient screens positive. At a minimum, the medical record must contain documentation of the tool's name and results of the screening with a score **OR** clinician interpretation of positive or negative for depression. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. A score interpreted as positive requires documentation of a follow-up plan. A score interpreted as negative does not require a follow-up plan. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have been diagnosed with depression or bipolar disorder will be excluded from the measure. **Added:** Follow-Up Plan: For a depression screen deemed positive, the follow-up plan MUST still be provided for and discussed with the patient during the qualifying encounter used to evaluate the numerator. However, documentation of the follow-up plan can occur up to two calendar days after the qualifying encounter, in accordance with the policies of an eligible clinician or provider's practice or health system. All services should be documented during, or as soon as practicable, after the qualifying encounter in order to maintain an accurate medical record.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise multiple components of the measure to add a grace period after the end of the encounter to document the follow-up plan, which would allow more flexibility in the clinical workflow giving clinicians time for documentation. This would ensure that those clinicians who meet the intent of the measure which is discussing a follow-up plan during the encounter, are not inadvertently marked as non-compliant due to delayed documentation. We propose to update the measure definition to improve alignment with measure intent which is to screen for new cases of depression in patients who have never had a diagnosis of depression or bipolar disorder, as well as to clarify the timing requirements of diagnoses for the measure exclusions. We propose to add coding for manic episodes to the Bipolar Diagnosis codes to align with measure intent which is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator.

E.3 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v10
Web Interface ID:	MH-1
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event.
Substantive Change:	**Updated denominator exclusion: Revised to read:** Patients with a diagnosis of bipolar disorder any time prior to the end of the measure assessment period Patients with a diagnosis of select personality disorders any time prior to the end of the measure assessment period Patients with a diagnosis of schizophrenia or psychotic disorder any time prior to the end of the measure assessment period Patients with a diagnosis of pervasive developmental disorder any time prior to the end of the measure assessment period Patients who were permanent nursing home residents any time during denominator identification period or the measure assessment period Patients with a diagnosis of personality disorder emotionally labile any time prior to the end of the measure assessment period **Updated denominator criteria: Added:** coding for preventive medicine encounters.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update coding for the denominator criteria to include preventive medicine encounters in order to engage patients and assess remission of depression. We propose to add timing information to the denominator exclusions to improve measure clarity and to align with the CQM version of the measure.

E.4 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v10
Web Interface ID:	CARE-2
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Updated initial population: Revised to read:** Patients aged 65 years and older at the start of the measurement period with a visit during the measurement period. **Updated value set/coding: Added:** coding for physical therapy and occupational therapy visits.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the initial patient population to change the age anchor from the start of the measurement period to the end of the measurement period so that it would align with HEDIS measure requirements and creates consistency for implementation across programs. Additionally, we propose to add occupational and physical therapy evaluation visits as applicable encounters as these clinicians interact with older adults that may be more susceptible to falls. Occupational therapists are "uniquely qualified to address the multifactorial nature of falls, given their knowledge of factors that influence occupational performance."[1] There is a strong body of evidence that supports the role of physical therapists in reducing fall risk and fall prevention as outlined within the American Physical Therapy Association (APTA) handout: https://www.apta.org/patient-care/public-health-population-care/balance-and-falls/research-on-falls#.

[1] Peterson, E. W., & Clemson, L. (2008). Understanding the role of occupational therapy in fall prevention for community-dwelling older adults. OT Practice, 13(3), CE1–CE8. https://www.researchgate.net/publication/286974169_Understanding_the_role_of_occupational_therapy_in_fall_prevention_for_community-dwelling_older_adults.

E.5 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v5
Web Interface ID:	PREV-13
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**Updated initial population: Revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients with a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated denominator: Revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients with a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes. **Updated submission guidance: Revised to read:** ○ Determine if the patient was previously diagnosed with or currently has a diagnosis of clinical ASCVD, including an ASCVD procedure at any time up through the last day of the measurement period **Removed:** **Active Diagnosis** is defined as a diagnosis that is either on the patient's problem list, a diagnosis code description listed on the encounter, or is documented in a progress note indicating that the patient is being treated or managed for the disease or condition at any time during the measurement period. **Updated denominator exclusion: Removed:** Patients who have a diagnosis of pregnancy at any time during the measurement period. **Updated definition: Added:** Ezetimibe / Rosuvastatin -- Roszet -- Fixed Dose Combination' to Table 1 - Statin Medication Therapy List. **Updated denominator exception: Added:** Patients with documentation of a medical reason for not being prescribed statin therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple sections to remove the word 'active' from the clinical diagnosis of ASCVD. ASCVD is a chronic condition, therefore a diagnosis of ASCVD at any time meets the intent of the initial population. We propose to remove the pregnancy exclusion to align with U.S Food and Drug Administration (FDA) recommendations that pregnancy be removed as a contraindication in prescribing statins (https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol). We also propose to update the definitions by adding another medication to the statin medication therapy list for completeness. We propose to update the denominator exceptions by adding a medical reason for not being prescribed statin therapy to align with American College of Cardiology/American Heart Association (ACC/AHA) guidelines (https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2019/03/07/16/00/2019-acc-aha-guideline-on-primary-prevention-gl-prevention).

E.6 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v11
Web Interface ID:	PREV-7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated measure reporting period: Revised:** Evaluates qualifying encounters that occur during either January through March of the measurement year or October through December of the measurement year to determine if that patient has received the influenza immunization for the relevant influenza season **Updated measure description: Revised to read:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization **Updated denominator: Revised to read:** Equals initial population (All patients aged 6 months and older seen for a visit during the measurement period) **Updated denominator note: Added:** For the purposes of the program, in order to submit on the flu season 2022-2023, the patient must have a qualifying encounter between January 1 and March 31, 2023. In order to submit on the flu season 2023-2024, the patient must have a qualifying encounter between October 1 and December 31, 2023. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period. **Updated measure guidance: Revised to read:** The numerator for this measure can be met by submitting either administration of an influenza vaccination or that the patient reported previous receipt of the current season's influenza immunization. If the performance of the numerator is not met, an eligible clinician can submit a valid denominator exception for having not administered an influenza vaccination. For eligible clinicians submitting a denominator exception for this measure, there should be a clear rationale and documented reason for not administering an influenza immunization if the patient did not indicate previous receipt, which could include a medical reason (e.g., patient allergy), patient reason (e.g., patient declined), or system reason (e.g., vaccination not available). The system reason should be indicated only for cases of disruption or shortage of influenza vaccination supply. Denominator Exception(s) are determined at the time of the denominator eligible encounter during the current flu season. **Removed:** Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV). **Updated definition: Revised to read: Previous Receipt** – receipt of the current season's influenza immunization from another provider OR from same provider prior to the visit to which the measure is applied
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise multiple sections of the measure to align with the CQM version of the measure. These changes allow for reporting receipt of influenza immunization for the two flu seasons that fall within a performance reporting period. Alignment with the CQM allows for reporting medical exceptions, and avoids eligible clinicians being penalized if not administering the influenza vaccine is medically and clinically appropriate. We propose to revise the guidance to remove the language for the LAIV formulation to align with current guidelines and would allow for the use of this formulation.

E.7 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v10
Web Interface ID:	PREV-5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated initial population: Revised to read:** Women 51 - 74 years of age on the date of the encounter with a visit during the measurement period. **Updated measure guidance: Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data

E.8 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v10
Web Interface:	PREV-6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer **Updated initial population: Revised to read:** Patients 45 to 75 years with a visit during the measurement period **Updated measure guidance: Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure description and initial population to align with the 2021 U.S. Preventive Services Task Force (USPSTF) guidelines that recommend Colorectal Cancer Screenings begin at age 45 rather than beginning at age 50. We propose to revise the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data.

E.9 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v10
Web Interface ID:	PREV-10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.
Substantive Change:	**Updated measure description: Revised to read:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user during the measurement period who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user **Updated denominator exception: Removed:** denominator exceptions. **Updated numerator: Revised to read:** For Submission Criteria 2: Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. For Submission Criteria 3: Patients who were screened for tobacco use at least once during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. **Updated measure definition: Revised to read:** Tobacco Use use of any tobacco product The 2021 USPSTF recommendation references the US Food and Drug Administration definition of tobacco which includes "any product made or derived from tobacco intended for human consumption (except products that meet the definition of drugs), including, but not limited to, cigarettes, cigars (including cigarillos and little cigars), dissolvables, hookah tobacco, nicotine gels, pipe tobacco, roll-your-own tobacco, smokeless tobacco products (including dip, snuff, snus, and chewing tobacco), vapes, electronic cigarettes (e-cigarettes), hookah pens, and other electronic nicotine delivery systems." The 2021 USPSTF recommendation describes smoking as generally referring to "the inhaling and exhaling of smoke produced by combustible tobacco products such as cigarettes, cigars, and pipes." The 2021 USPSTF recommendation describes vaping as "the inhaling and exhaling of aerosols produced by e-cigarettes." In addition, it states, "vaping products (that is, e-cigarettes) usually contain nicotine, which is the addictive ingredient in tobacco. Substances other than tobacco can also be used to smoke or vape. While the 2015 USPSTF recommendation statement used the term 'electronic nicotine delivery systems' or 'ENDS,' the USPSTF recognizes that the field has shifted to using the term 'e-cigarettes' (or 'e-cigs') and uses the term e-cigarettes in the current recommendation statement. e-Cigarettes can come in many shapes and sizes, but generally they heat a liquid that contains nicotine (the addictive drug in tobacco) to produce an aerosol (or 'vapor') that is inhaled ('vaped') by users." Tobacco Cessation Intervention Includes brief counseling (3 minutes or less), and/or pharmacotherapy -- Note: Concepts aligned with brief counseling (e.g., minimal and intensive advice/counseling interventions conducted both in person and over the phone) are included in the 2023 CMS Web Interface PREV-10 Coding Document for the numerator. Other concepts such as written self-help materials (for example., brochures, pamphlets) and complementary/alternative therapies are not included in the 2023 CMS Web Interface PREV-10 Coding Document and do not qualify for the numerator. Counseling also may be of longer duration or be performed more frequently, as evidence shows that higher-intensity interventions are associated with higher tobacco cessation rates (U.S. Preventive Services Task Force, 2021). **Updated guidance: Revised to read:** The requirement of two or more visits is to establish that the eligible clinician has an existing relationship with the patient for certain types of encounters. To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the measurement period. If a patient has multiple tobacco use screenings during the measurement period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. If a patient uses any type of tobacco (i.e., smokes or uses smokeless tobacco), the expectation is that they should receive tobacco cessation intervention: either counseling and/or pharmacotherapy. As noted in Appendix III in the 2021 USPSTF recommendation statement, the current evidence is insufficient to recommend electronic cigarettes (e-cigarettes) for tobacco cessation. However, as noted above in the Definition section, the 2021 USPSTF recommendation also references the US Food and Drug Administration definition of tobacco, which includes e-cigarettes, hookah pens and other electronic nicotine delivery systems. Therefore, the measure does consider the use of e-cigarettes and other electronic nicotine delivery systems to be tobacco use.

Category	Description
	If a patient's tobacco use status is unknown, the patient does not meet the screening requirement and does not meet the numerator for populations 1 or 3. Instances where tobacco use status of "unknown" include: 1) the patient was not screened; or 2) the patient was screened and the patient (or caregiver) was unable to provide a definitive answer. In order to promote a team-based approach to patient care, the tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. This measure contains three reporting rates which aim to identify patients who were screened for tobacco use (rate/population 1), patients who were identified as tobacco users and who received a tobacco cessation intervention (rate/population 2), and a comprehensive look at the overall performance on tobacco screening and cessation intervention (rate/population 3). By separating this measure into various reporting rates, the eligible clinician will be able to better ascertain where gaps in performance exist, and identify opportunities for improvement. The overall rate (rate/population 3) can be utilized to compare performance to published versions of this measure prior to the 2018 performance year, when the measure had a single performance rate. For accountability reporting in the CMS Medicare Shared Savings Program, the rate for population 2 is used for performance. The denominator of population criteria 2 is a subset of the resulting numerator for population criteria 1, as population criteria 2 is limited to assessing if patients identified as tobacco users received an appropriate tobacco cessation intervention. For all patients, population criteria 1 and 3 are applicable, but population criteria 2 will only be applicable for those patients who are identified as tobacco users. Therefore, data for every patient that meets the initial population criteria will only be submitted for population 1 and 3, whereas data submitted for population 2 will be for a subset of patients who meet the initial population criteria, as the denominator has been further limited to those who were identified as tobacco users. **Updated denominator criteria: Added:** coding for registered dietitians and nutritionists.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of the measure to better define and align the lookback period for tobacco cessation intervention and to allow a lookback of 6-months prior to the current measurement period. We propose to update the denominator statement for Population 2 to clarify the timing of the screening for tobacco cessation intervention. We are proposing to update the denominator criteria to include encounter codes for registered dieticians and nutritionists to allow them to screen for tobacco use as part of a comprehensive patient assessment. Additionally, we propose to remove all denominator exceptions. The measure definition is also being updated to align with 2021 USPSTF recommendations.

E.10 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v10
Web Interface ID:	HTN-2
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Web Interface
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated guidance: Added:** Ranges and thresholds do not meet criteria for this measure. A distinct numeric result for both the systolic and diastolic BP reading is required for numerator compliance. **Revised to read:** To assess the age for exclusions, the patient's age on the date of encounter should be used.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to revise the denominator guidance to allow for the age to be determined at the time of the denominator eligible encounter. This would reduce clinician burden regarding age calculations for the purposes of determining applicability of the denominator exclusions and would allow for better alignment with clinical guidelines, for age criteria, when utilizing this collection type. This would help to ensure the appropriate patient population is being assessed for the quality action resulting in meaningful data. We propose to add language to ensure that only distinct numeric results are being utilized for the purpose of this measure as ranges and thresholds do not meet the measure's intent.

APPENDIX 2: IMPROVEMENT ACTIVITIES

NOTE: In this proposed rule, for the CY 2023 performance period/2025 MIPS payment year and future years, we are proposing to add four new improvement activities, modify five previously adopted improvement activities, and remove six previously adopted improvement activities. These proposals are discussed in detail below. We request comment on our proposals.

Table A: Proposed New Improvement Activities for the CY 2023 Performance Period/CY 2025 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data
Proposed Activity Description:	Use security labeling services available in certified health Information Technology (IT) for electronic health record (EHR) data to facilitate data segmentation.
Proposed Weighting:	Medium
Rationale:	Data segmentation capabilities are used to promote interoperability while preserving confidentiality, honoring consent, and respecting patient privacy preferences. This new activity would promote the adoption of technology certified to the Security tags - summary of care send and Security tags – summary of care – receive criteria at 45 CFR 170.315(b)(7) and (b)(8) in the ONC Health IT Certification Program.[1] Security tagging allows sharing of certain portions of an EHR while not sharing others, such as sensitive information related to substance use disorder treatment. This activity would involve clinicians working with their EHR vendors to implement technology meeting the security tags criteria at 45 CFR 170.315 (b)(7) and (b)(8) in practice systems and clinic workflows, and in so doing improving interoperability while protecting patient privacy. Health IT certified to these criteria is not required for participation in the Promoting Interoperability performance category. This improvement activity fills a gap in the Inventory, as there is no existing improvement activity that focuses on security labeling services and/or data segmentation. We propose weighting this activity medium because this activity may be accomplished by working with clinicians' EHR vendors to implement security tags criteria at 45 CFR 170.315 (b)(7) and (b)(8) in practice systems and clinic workflows. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the Inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
Proposed Activity Description:	Create and implement a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population. The plan may include an analysis of sexual orientation and gender identity (SO/GI) data to identify disparities in care for LGBTQ+ patients. Actions to implement this activity may also include identifying focused goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and the Office of the National Coordinator for Health Information Technology [2] US Core Data for Interoperability [USCDI]), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories.

Proposed Weighting:	High
Rationale:	LGBTQ+ individuals face health disparities and challenges navigating and accessing healthcare.[3, 4] Due to lack of clinician training about providing care with cultural humility and sensitivity for LGBTQ+ individuals, several studies indicate that LGBTQ+ patients, especially gender minority patients, have high rates of negative healthcare experiences.[5-7] Compared with heterosexual individuals, LGBTQ+ individuals in the U.S. generally have lower life expectancies, higher rates of cardiovascular disease, gynecologic cancer, breast cancer, body issues and eating disorders, substance use, and mental health conditions, including anxiety, depression, suicidal ideation, and non-suicidal self-injury.[3, 8] In 2015, ONC issued a final rule requiring that certified health IT enable a user to record sexual orientation and gender identity (SO/GI), but users were not required to exchange these data (45 CFR Parts 170 and 171).[9] In the first year after implementation, sexual orientation data were missing for 75% of patients and gender identity data were missing for 65% of patients.[10] Clinicians have increasing opportunities to improve data collection, as adoption of the USCDI Version 2 within certified health IT will offer improved support for the exchange of SO/GI data elements. Increasing patients' and clinicians' comfort with and knowledge about SO/GI data collection can also improve data collection.[3, 11] This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on improving care for LGBTQ+ patients. We believe this activity has the potential to improve clinical practice and care delivery because training clinicians about serving LGBTQ+ patients can lead to more positive care experiences.[6, 12] Understanding disparities in care access, screenings, and health outcomes and implementing a plan to address identified health disparities can improve the care LGBTQ+ patients receive.[11, 13] We propose weighting this activity high because clinicians will need considerable time and resources to develop a thorough LGBTQ+ care improvement plan that is informed by data, and to implement it throughout the practice or system. See the definition of high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_EPA_XX**
Proposed Subcategory:	Expanded Practice Access
Proposed Activity Title:	Create and Implement a Language Access Plan
Proposed Activity Description:	Create and implement a language access plan to address communication barriers for individuals with limited English proficiency. The language access plan must align with standards for communication and language assistance defined in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (https://thinkculturalhealth.hhs.gov/clas).
Proposed Weighting:	High
Rationale:	We believe the evidence is clear that accurate patient-clinician communication, delivered and received with cultural humility, is an essential aspect of improving equity in healthcare and patient outcomes.[14, 15] According to the 2020 U.S. Census, 8.3 percent of American households speak English "less than very well" and are thus said to be limited English-proficient (LEP).[16] "The ability to communicate with a healthcare clinician can mean the difference between receiving higher or lower quality care."[14] The use of properly trained medical interpreters is superior to use of ad hoc, family, or no interpreters.[17] Use of professional interpreter services improves patient and clinician satisfaction with communication[18] and improves patient safety.[19] A language access plan can help clinician organizations codify the process that will be used to provide services to individuals with limited English proficiency. A language access plan typically contains information on beneficiary needs, defines how interpretation will be provided, outlines how patients and families will be notified about interpretation services, and specifies staff training.[20] The plan may include policies and procedures regarding the use of professional interpreters, high-quality translation of

	patient materials, and collection of patients' language preference. The plan may also include details on communication with individuals who are deaf, hard of hearing, and deaf-blind.[21] The National CLAS Standards include four standards on communication and language assistance that stipulate: language assistance should be timely and offered at no cost; patients should be informed that language assistance is available; competent individuals provide translation and interpretation services; and materials and signage are printed in commonly used languages.[22, 23] This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on language access. We believe this activity has the potential to improve clinical practice and care delivery and is likely to result in improved patient outcomes, because research demonstrates the importance of accurate clinical communication in achieving positive patient outcomes.[14, 15] We propose making this activity high-weighted because clinicians will need considerable time and resources to develop a thorough language access plan that is informed by data, and to implement it throughout the practice or system. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_XX**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	COVID-19 Vaccine Achievement for Practice Staff
Proposed Activity Description:	Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100% of office staff in the MIPS eligible clinician's practice fully COVID-19 vaccinated according to the Center for Disease Control and Prevention's definition of fully vaccinated (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html).
Proposed Weighting:	Medium
Rationale:	COVID-19 vaccination rates in the U.S. can be improved significantly, particularly in communities that are disadvantaged and/or underserved by the healthcare system.[24] Disparities in COVID-19 vaccination rates have been observed specifically among healthcare workers, with physicians and advanced practiced staff being more likely to be vaccinated than nurses and support staff. Also, it has been reported that Black and younger health care workers have lower vaccination rates than other groups of healthcare workers.[25] We are recommending this new improvement activity be focused on achieving or maintaining 100% COVID-19 vaccination for practice staff. This improvement activity would fill a gap in the Inventory, which does not currently include an activity focused on COVID-19 vaccination achievement. We believe this activity has the potential to improve clinical practice and is likely to result in improved outcomes and public health, because research demonstrates the importance of vaccination in reducing the severity and spread of COVID-19.[26] We propose weighting this activity medium, because this activity may be accomplished by vaccinating all staff members and tracking the vaccination status of each office staff member in practice staff records. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the Inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).

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Table B: Proposed Changes to Previously Adopted Improvement Activities for the CY 2023 Performance Period/CY 2025 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_CC_13**
Current Subcategory:	Care Coordination
Current Activity Title:	Practice Improvements for Bilateral Exchange of Patient Information
Current Activity Description:	Ensure that there is bilateral exchange of necessary patient information to guide patient care, such as OpenNotes, that could include one or more of the following: • Participate in a Health Information Exchange if available; and/or • Use structured referral notes.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 Performance Period/CY 2019 MIPS Payment Year (81 FR 77817 through 77830). We propose updating this activity to require the use of OpenNotes to reduce clinician burden because OpenNotes focuses on principles that support direct access to medical records rather than utilizing a specific software or product. OpenNotes aligns with relevant policies described in the 21st Century Cures Act (Pub. L. 114–255) that aim to make direct access to medical records a best practice in the field. Updating this activity to require the use of OpenNotes will reflect advances in policy and practice, particularly regarding the importance of direct patient-clinician communication and ensuring that patients are at the center of their care.
Proposed Revised Activity Title:	Practice Improvements to Align with OpenNotes Principles
Proposed Revised Activity Description:	Adherence to the principles described in the OpenNotes initiative (https://www.opennotes.org) to ensure that patients have full access to their patient information to guide patient care.
Current Improvement Activity	
Current Activity ID:	IA_CC_14
Current Subcategory:	Care Coordination
Current Activity Title:	Practice improvements that engage community resources to support patient health goals
Current Activity Description:	Select and screen for the health-related social needs (HRSN) that are relevant for your patient population using tools that have been tested with underserved populations. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded question/field for the capture of data. After screening, address HRSNs identified through at least one of the following: • Maintain formal relationships with community- based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Update a guide to available community resources, or work with community partners to provide a community resource guide and provide it to patients who are found to be at risk in one or more HRSN area; or • Record findings of screening and trigger follow-up within the electronic health record (EHR); then analyze EHR data on patients with one or more HRSN needed to identify and implement approaches to better serve their holistic needs through linkages with community resources. HRSNs prioritized by your practice might include health-harming legal needs, which require both health and legal support to resolve, areas such as food and housing insecurity, or needs such as exercise, nutrition, or chronic disease self-management.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 Performance Period/CY 2019 MIPS Payment Year (81 FR 77817 through 77830). We are proposing to modify the activity title and description to refer to 'drivers of health,' which encompasses both 'social determinants of health (SDOH)' and 'health-related social needs (HSRN)' concepts. Drivers of health are the multitude of factors that impact each other and overall human health, which often include health behavior, social and economic environment, clinical care, and physical environment.[1] Drivers of health may be direct, such as health behaviors or access to health care, or indirect, such as income,

	education, or occupation, which may not necessarily impact health in an immediate way.[2,3] They may also be at the individual or community level.[4] We are also proposing to update the list of factors in the activity description to reflect a more comprehensive array of the drivers of health that align with related activities across CMS and HHS by removing "or needs such as exercise, nutrition, or chronic disease self-management" and replacing it with "transportation accessibility; interpersonal safety; legal challenges; and environmental exposures."[1-3] We added language prior to this list noting drivers of health "are not limited" to those in the description, as eligible clinicians can select other drivers of health. We are also proposing to update the activity ID and subcategory to Achieving Health Equity (AHE) due to the connection between drivers of health, health equity, and improved health outcomes.[5,6] We believe the proposed modifications would better enable eligible clinicians to not only improve clinical practice by screening for and addressing drivers of health, but to also receive credit for their efforts.[4] Furthermore, we anticipate such efforts would be associated with improved clinical outcomes because of the recognized impact of drivers of health and other upstream factors on both healthcare and health status.[5-8] Finally, these proposed modifications would also more clearly align this activity with the evidence base described above[1-6] and other CMS work in this area, including the CMS Innovation Center's Accountable Health Communities (AHC) Model, designed to test how "addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs."[7]
Proposed Revied Activity ID:	IA_AHE_XX
Proposed Revised Activity Subcategory:	Achieving Health Equity
Proposed Revised Activity Title:	Practice Improvements that Engage Community Resources to Address Drivers of Health
Proposed Revised Activity Description:	Select and screen for drivers of health that are relevant for the eligible clinician's population using evidence-based tools. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded questions/fields for the capture of data. After screening, address identified drivers of health through at least one of the following: • Develop and maintain formal relationships with community-based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Work with community partners to provide and/or update a community resource guide for to patients who are found to have and/or be at risk in one or more areas of drivers of health; or • Record findings of screening and follow up within the electronic health record (EHR); identify screened patients with one or more needs associated with drivers of health and implement approaches to better serve their holistic needs through meaningful linkages to community resources. Drivers of health (also referred to as social determinants of health [SDOH] or health-related social needs [HSRN]) prioritized by the practice might include, but are not limited to, the following: food security; housing stability; transportation accessibility; interpersonal safety; legal challenges; and environmental exposures.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status

	assessment); • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing to consolidate IA_BE_7, IA_BE_8, and IA_PM_7 related to participation in a QCDR into a single activity, IA_PSPA_7. We note that this proposed modification is being made in conjunction with our proposals to remove IA_BE_7, IA_BE_8, and IA_PM_7 in Table C. This consolidation will reduce clinician burden by streamlining the choice for a QCDR activity and make IA_PSPA_7 more robust and offer additional examples. We believe this would help to enhance patient engagement, learning and practice improvement, progress in improving health equity, and population health management by creating standard processes to monitor, assess, and improve practice activities. We believe these proposed modifications have the potential to improve clinical practice and are likely to result in improved outcomes, because they focus on creating ongoing activities aimed at identifying gaps and improving processes to support patient safety and equitable provision of care. Note that the weighting of the consolidated activity would remain as medium, because the level of effort to attest to this activity would be the same as for IA_PSPA_7. See the definition for medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools, and processes for quality improvement (for example, documented preventive health efforts, like screening and vaccinations) that can be shared across MIPS eligible clinicians or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment); • Use of standardized processes for screening for drivers of health, such as food security, housing stability, and transportation accessibility; • Generation and use of regular feedback reports that summarize local practice patterns and treatment outcomes, including for populations that are disadvantaged and/or underserved by the healthcare system; • Use of processes and tools that engage patients to improve adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision-making capabilities; • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; • Promotion of collaborative learning network opportunities that are interactive; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement, such as comparative analysis across specific patient populations of adverse outcomes after an outpatient surgical procedure and corrective steps to address these outcomes.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_10**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of training and receipt of approved waiver for provision opioid medication-assisted treatments
Current Activity Description:	Completion of training and obtaining an approved waiver for provision of medication - assisted treatment of opioid use disorders using buprenorphine.

Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 Performance Period/CY 2019 MIPS Payment Year (81 FR 77817 through 77830). We are proposing to modify this improvement activity to incorporate HHS Office of the Secretary Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (86 FR 22439) updates that removed the 8-hour training requirement for physicians.[9] We are also proposing to add a note limiting the attestation of this improvement activity to once for low-capacity waivers because they never expire and once every 3 years for the expanded waiver. These limitations are in line with the renewal requirements of the waiver (86 FR 22439) and ensure clinicians are able to perform the improvement activity for a 90-day continuous period as required by 42 CFR 414.1360. In addition, we are proposing to re-categorize this activity to the Behavioral and Mental Health subcategory, which we believe better reflects the intent of this improvement activity, because it is focused on improving treatment for opioid use disorder, a behavioral and mental health condition. We believe the proposed modifications to this activity have the potential to improve clinical practice and are likely to result in improved outcomes, because it will reduce clinician burden by streamlining the activity to align with federal guidance and ensure that patients are receiving medication-assisted treatment in line with medical guidelines.
Proposed Activity ID	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Revised Activity Title	Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder
Proposed Revised Activity Description:	Complete any required training and obtain or renew an approved waiver for provision of medication-assisted treatment of opioid use disorders using buprenorphine. Note: This activity may be selected once for low-capacity waivers, as these do not expire, and once every 3 years for the expanded waiver, in keeping with renewal requirements.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_19**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participate in multisource feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participate in Bridges to Excellence; • Participate in the American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized for the CY 2017 Performance Period/CY 2019 MIPS Payment Year (81 FR 77817 through 77830). In Table C below, we are proposing to remove IA_PSPA_20, "Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes" and consolidate it with IA_PSPA_19. Specifically, we are proposing to consolidate IA_PSPA_20 into IA_PSPA_19 by adding the following language about leadership from IA_PSPA_20 to IA_PSPA_19's activity description: "including leadership" after "staff." This addition will reduce clinician burden by broadening IA_PSPA_19 and

	making it more robust. Note that the weighting of the modified activity would remain as medium, because the level of effort to attest to this activity would be the same as it was previously. See the definition for medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Proposed Revised Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff, including leadership, actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence; • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.

[1] Melton, C. (2018). *The drivers of health*. https://www.sycamoreinstitutetn.org/drivers-of-health/#:~:text=Our%20social%20and%20economic%20environments,greatest%20predictors%20of%20their%20health.

[2] Drivers of Health. (2022). *The framework*. https://driversofhealth.org/the-framework/

[3] Raphael, K., Frakt, A., Jha, A., & Glied, S. (2019). *Social and health-systems factors that affect health: What's known and knowable? A review of literature*. https://driversofhealth.org/wp-content/uploads/SDH.whitepaper_v8.pdf

[4] Lumpkin, J. R., Perla, R., Onie, R., & Seligson, R. (2021). *What we need to be healthy—and how to talk about it*. https://www.healthaffairs.org/do/10.1377/forefront.20210429.335599/full/

[5] Gómez, C. A., Kleinman, D. V., Pronk, N., Wrenn Gordon, G. L., Ochiai, E., Blakey, C., Johnson, A., & Brewer, K. H. (2021). Addressing health equity and social determinants of health through healthy people 2030. *Journal of Public Health Management and Practice*, *27*, S249-S257. https://doi.org/10.1097/phh.0000000000001297

[6] Artiga, S., & Hinton, E. (2018). *Beyond health care: The role of social determinants in promoting health and health equity*. https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/

[7] Centers for Medicare & Medicaid Services. (2022). *Accountable health communities (ach) model*. https://innovation.cms.gov/innovation-models/ahcm

[8] Thornton, R. L., Glover, C. M., Cené, C. W., Glik, D. C., Henderson, J. A., & Williams, D. R. (2016). Evaluating strategies for reducing health disparities by addressing the social determinants of health. *Health Affairs*, *35*(8), 1416-1423. https://doi.org/10.1377/hlthaff.2015.1357

[9] Cleary, E. M., Smid, M. C., Charles, J. E., Jones, K. M., Costantine, M. M., Saade, G., & Rood, K. M. (2021). Buprenorphine x-waiver exemption - beyond the basics for the obstetrical provider. *American Journal of Obstetrics and Gynecology*, *3*(6), 100451. https://doi.org/10.1016/j.ajogmf.2021.100451

TABLE C: Improvement Activities Proposed for Removal for the CY 2023 Performance Period/CY 2025 MIPS Payment Year and for Future Years

In this rule, we are proposing to remove six previously finalized improvement activities from the CY 2023 performance period/CY 2025 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision-making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_BE_7 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we are proposing to add "Use of processes and tools that engage patients for adherence to treatment plans; Implementation of patient self-action plans; Implementation of shared clinical decision-making capabilities; Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_BE_7. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_8 and IA_PM_7 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_BE_8**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
Current Activity Description:	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_BE_8 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we are proposing to modify IA_PSPA_7 to add "promotion of collaborative learning network opportunities that are interactive" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_BE_8. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_7 and IA_PM_7 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_PM_7**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR for feedback reports that incorporate population health
Current Activity Description:	Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.
Current Weighting:	High
Removal Rationale:	We propose to remove this activity under removal factor one, improvement activity is "duplicative." We believe IA_PM_7 is duplicative because it is similar to, but only represents a partial component of, IA_PSPA_7. In Table B above, we are proposing to

	add "generation and use of regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_PM_7. We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to remove IA_BE_7 and IA_BE_8 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_6**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consultation of the Prescription Drug Monitoring program
Current Activity Description:	Review the history of controlled substance prescriptions for 90 percent* of patients using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. *Apply exceptions for patients receiving palliative and hospice care.
Current Weighting:	High
Removal Rationale:	We propose to remove this activity under removal factor one, improvement activity is "duplicative." IA_PSPA_6 would be duplicative of the proposal to require the Query of PDMP measure for MIPS eligible clinicians in the Promoting Interoperability performance subcategory (measure PI_EP_2). The removal of this activity is contingent upon the proposal in section V.A.10.c.(4)(d)(i)(D)(ab) of this proposed rule.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_20**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes
Current Activity Description:	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: • Make responsibility for guidance of practice change a component of clinical and administrative leadership roles; • Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or • Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor one, improvement activity is "duplicative." We note that this proposed removal is being made in conjunction with our proposal to modify IA_PSPA_19 in Table B by adding the phrase "including leadership" to the activity description after "staffing" to capture the essence of IA_PSPA_20. We believe that this activity would be duplicative of IA_PSPA_20 upon the adoption that proposal because it is similar to, but would only represent a partial component of, IA_PSPA_19.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_30**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	PCI Bleeding Campaign
Current Activity Description:	Participation in the PCI Bleeding Campaign which is a national quality improvement program that provides infrastructure for a learning network and offers evidence-based resources and tools to reduce avoidable bleeding associated with patients who receive a percutaneous coronary intervention (PCI). The program uses a patient-centered and team-based approach, leveraging evidence-based best practices to improve care for PCI patients by implementing quality improvement strategies: • Radial-artery access, • Bivalirudin, and • Use of vascular closure devices.
Current Weighting:	High
Removal Rationale:	We propose to remove this activity under removal factor seven, improvement activity is "obsolete." The PCI Bleeding Campaign concluded on August 31, 2021,[1] so this

	improvement activity will no longer be available as of the conclusion of the 2022 performance period. This proposal would apply beginning with the CY 2022 performance period/CY 2024 payment year.

[1] Quality Improvement for Institutions. (n.d.). *Sunsetting the reduce the risk: Pci bleed dashboard.* https://cvquality.acc.org/initiatives/reduce-the-risk-pci-bleed.

APPENDIX 3: MVP INVENTORY

MVP Development Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854) and CY 2022 PFS final rule (86 FR 65998 through 66031) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements and selection of measures and activities within an MVP. In addition, in section IV.A.8. of this proposed rule, we are proposing additional MVP policies, which if finalized would further explain the MVP development, maintenance, and reporting requirements.

This appendix contains two groups of proposed MVP tables: Group A, proposed new MVPs and Group B, proposed modifications to previously finalized MVPs. Group A includes five new proposed MVPs. Group B includes seven previously finalized MVPs with proposed modifications.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, each MVP includes a foundational layer that is comprised of population health measures and Promoting Interoperability performance category measures.

In the CY 2022 PFS final rule, we inadvertently omitted the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) from the MVP tables in Appendix 3 (86 FR 66002 through 66031). In the CY 2021 PFS final rule (85 FR 84849 through 84850), as a part of the MVP development criteria, we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described under § 414.1375(b). The ONC Direct Review attestation requirement has been a requirement for the Promoting Interoperability performance category since the first MIPS performance period in CY 2017 (81 FR 77019 through 77028). For these reasons, we propose to add the ONC Direct Review attestation requirement described under § 414.1375(b)(3) to all previously finalized MVPs and newly proposed MVPs.

In addition, we now propose to include the IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation improvement activity in all previously finalized MVPs and newly proposed MVPs in alignment with policy finalized in the CY 2017 MIPS final rule (81 FR 77179 through 77180): MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary and codified at 414.1480(b)(3)(ii), may attest to this activity and receive an improvement activities performance category score of 100 percent.

MVP Development Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures are located in the 2022 MIPS Quality Measures List in the QPP Resource Library.[1] In addition, see Appendix 1: MIPS Quality Measures of this proposed rule for any proposed modifications to the existing quality measures.
- Existing QCDR measures are based on the most recent publication of the 2022 QCDR Measure Specification file and is located in the QPP Resource Library.[2] We plan to modify the list of 2023 QCDR measures around December 2022.
- Improvement activities are located in the 2022 Improvement Activities Inventory, and the 2022 MIPS Data Validation Criteria are located in the QPP Resource Library.[3] In addition, see Appendix 2: Improvement Activities of this proposed rule for any proposed removals, additions, or modifications to the existing activities.
- Existing cost measures are located in the 2022 Cost Measures Inventory.[4]
- For further details on the population health measures included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located in the QPP Resource Library.[5] In addition, see section IV.A.10.c.(4) of this proposed rule for proposals regarding the existing Promoting Interoperability measures.

Please note that new quality and Promoting Interoperability measures proposed for inclusion in MIPS beginning with the CY 2023 performance period/2025 MIPS payment year and future years are identified with a caret symbol (^) within the MVP tables in this appendix. Existing quality measures, improvement activities, and Promoting Interoperability measures with proposed revisions are identified with an asterisk (*) within the MVP tables in this appendix. Quality measures identified with a double asterisk (**) are individual measures duplicating a component of the proposed composite Adult Immunization Status measure. If the Adult Immunization Status measure is finalized, the quality measures that include the (**) can only be submitted when included in an MVP. Please see Appendix 1: MIPS Quality Measures Table A.9 of this proposed rule for any additional information regarding the proposed Adult Immunization Status measure. Quality measures, Promoting Interoperability attestation requirements, and improvement activities that we are proposing to add to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

Quality measures that are considered high priority (as defined in § 414.1305) are noted with an exclamation point (!) and outcome measures (as defined in § 414.1305) are noted with a double exclamation point (!!). In addition, see section IV.A.10.c.(1)(b)(i) of this proposed rule for proposals regarding expansion of the definition of a high priority measure. Further details on these types of measures are located in the CMS Measures Management System Blueprint Version 17.0.[6] Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

- QCDR measures proposed in the MVP tables below that are noted with a pound sign (#) indicate that testing data is still pending and due on or before September 1, 2022. We refer readers to the CY 2022 PFS final rule for additional details regarding requirements for QCDR measures considered for an MVP (86 FR 65407 through 65408).
- Consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," each MVP includes improvement activities designed to advance health equity and address and eliminate barriers to care in underserved communities. Improvement activities that include a health equity component are noted with a tilde (~) within the MVP table. The improvement activities that include a health equity component are not required but are available as an option within the MVPs. Improvement activity medium/high weight designations are identified in parentheses after each improvement activity. IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is noted with a percent (%) within the MVP tables below to indicate that attestation to this improvement activity provides full credit for the improvement activity performance category within the MVP.

[1] See the 2022 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1687/2022%20MIPS%20Quality%20Measures%20List.xlsx.
[2] See https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1697/2022%20QCDR%20Measure%20Specifications.xlsx for QCDR measures.
[3] See the 2021 Improvement Activities Inventory: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1727/2022%20Improvement%20Activities%20Inventory.zip 2021 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1780/2022%20MIPS%20Data%20Validation%20Criteria.zip for improvement activity details.
[4] See the 2022 Cost Measures Inventory: https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2022.
[5] See the 2022 MIPS Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1733/2022%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip for Promoting Interoperability measure details.
[6] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.

Group A: New MVPs Proposed for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

A.1 Advancing Cancer Care MVP

In support of the Administration's Cancer Moonshot Mission[7] and the importance of cancer care, we are proposing the Advancing Cancer Care MVP. The proposed Advancing Cancer Care MVP focuses on the clinical theme of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practice of oncology and hematology.

Quality Measures

We propose to include eleven MIPS quality measures and two QCDR measures within the quality component of this MVP, which are specific to the clinical topic of cancer by assessing three critical areas: the patient experience of care, end of life care, and appropriate diagnostics along with possible treatment options for different cancer diagnoses. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with oncologic conditions:

- Q143: Oncology: Medical and Radiation – Pain Intensity Quantified: This MIPS quality measure ensures pain intensity is assessed and quantified in those patients receiving chemotherapy or radiation.
- Q144: Oncology: Medical and Radiation – Plan of Care for Pain: This MIPS quality measure ensures a plan of care is in place for those patients experiencing pain while receiving chemotherapy or radiation.
- Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer: This MIPS quality measure ensures appropriate treatment for this patient population in accordance with guidelines.
- Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy: This MIPS quality measure strives to improve concordance with RAS (KRAS and NRAS) testing guidelines for metastatic colorectal cancer patients, by assessing if gene mutation testing was performed prior to therapy.
- Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies: This MIPS quality measure ensures patients with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation are not treated inappropriately with anti-EGFR monoclonal antibodies.
- Q453: Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better): This MIPS quality measure assesses appropriate end of life care for cancer patients by reducing the utilization of unnecessary chemotherapy.
- Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better): This MIPS quality measure assesses appropriate end of life care for cancer patients by increasing the use of hospice services sooner for patients with advanced cancer.
- Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: This MIPS quality measure ensures proper bone density evaluation for patients with a care plan including androgen deprivation therapy for 12 or more months to promote positive bone health outcomes.
- PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer: This QCDR measure assesses clinical practice guideline compliance regarding implementation of mutations testing to optimize diagnosis and disease management.
- PIMSH8: Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy: This QCDR measure assesses the use of GCSFs in accordance with current guidelines.

In conjunction with the aforementioned cancer care measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to cancer care. The quality measures below capture the patient's voice regarding their care and support the mental health of patients that are experiencing a cancer diagnosis:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey provides direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include thirteen improvement activities that reflect actions and processes undertaken by clinicians who provide cancer care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement

activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for cancer patients. The following improvement activities are proposed for inclusion in this MVP:

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_BE_24: Financial Navigation Program
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_17: Patient Navigator Program
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_15: Implementation of episodic care management practice improvements
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_16: Use of decision support and standardized treatment protocols

Cost Measures

Within the cost component of this MVP, we propose to include the Total Per Capita Cost (TPCC) measure because it captures the overall costs of care after establishing a primary care-type relationship. This includes the care provided to patients by medical, hematological, and gynecological oncologists. The broad focus of the measure, which includes total costs of care for patients with cancer, supports the intent of this MVP to apply to cancer care. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

[7] See https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/.

TABLE A.1: Advancing Cancer Care MVP

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Advancing Cancer Care MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (!) **Q144:** Oncology: Medical and Radiation – Plan of Care for Pain (Collection Type: MIPS CQMs Specifications) (*)(!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (!) **Q450**: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **Q451**: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_17:** Patient Navigator Program (High) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Total Per Capita Cost (TPCC)**

Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q452:** Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies (Collection Type: MIPS CQMs Specifications) **(*)(!) Q453:** Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) **(!!) Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(#)(!) PIMSH2:** Oncology: Utilization of GCSF in Metastatic Colorectal Cancer (Collection Type: QCDR) **(#)(!) PIMSH8:** Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy (Collection Type: QCDR)	**IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review	

A.2 Optimal Care for Kidney Health MVP

The proposed Optimal Care for Kidney Health MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This proposed MVP would be most applicable to clinicians who treat patients within the practice of nephrology.

Quality Measures

We propose to include eight MIPS quality measures within the quality component of this MVP, which promote the management and risks associated with kidney disease. We reviewed the MIPS quality measure inventory and believe the following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with kidney disease conditions:

- Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): This MIPS quality measure assesses diabetic patients for hemoglobin A1c control.
- Q482: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate: This MIPS quality measure represents an intermediate outcome for maintenance hemodialysis patients by assessing for continuous catheter use.
- TBD: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy: This MIPS quality measure assesses for the prescribing of an ACE inhibitor or ARB therapy for patients diagnosed with chronic kidney disease (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria.

In conjunction with the aforementioned nephrological measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to kidney care. The quality measures below capture the patient's voice regarding their care, the assessment and administration of the influenza and pneumococcal vaccinations, documentation of current medications, and blood pressure control—all of which support the safety and general health of patients that are experiencing disease of the kidney:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q110: Preventive Care and Screening: Influenza Immunization: This MIPS quality measure assesses for the administration or previous receipt of the influenza immunization for pediatric and adult patients.
- Q111: Pneumococcal Vaccination Status for Older Adults: This MIPS quality measure assesses that patients receive the pneumococcal vaccinations.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q236: Controlling High Blood Pressure: This MIPS quality measure promotes controlling blood pressure in patients diagnosed with essential hypertension with a goal to maintain a systolic pressure of < 140 mmHg and diastolic pressure of < 90 mmHg.

In developing this proposal, we also considered including the following quality measure for this proposed MVP. However, we ultimately decided not to include it because the clinical action represented within this measure would most likely be performed by a primary care clinician and would support the referral of the patient to a nephrologist for their initial assessment. Therefore, this measure would likely not be appropriate for this MVP topic due to the quality action being more frequently performed by primary care rather than the nephrologist.

- TBD: Kidney Health Evaluation: This MIPS quality measure assesses patients that are diagnosed with diabetes for receipt of a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) and Urine Albumin-Creatinine Ratio (uACR).

Improvement Activities

Within the improvement activities component of this MVP, we propose to include thirteen improvement activities that reflect actions and processes undertaken by clinicians who specialize in treating patients with kidney disease conditions, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care patients with kidney disorders. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_14: Engage Patients and Families to Guide Improvement in the System of Care
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_BE_16: Promote Self-management in Usual Care
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_13: Practice Improvements for Bilateral Exchange of Patient Information
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation

- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_16: Use of decision support and standardized treatment protocols

Cost Measures

Within the cost component of this MVP, we propose two measures: The Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis episode-based cost measure and Total Per Capita Cost (TPCC) measure. The AKI Requiring New Inpatient Dialysis episode-based measure applies to nephrologists and other clinicians providing hemodialysis or dialysis procedures for acute kidney failure during inpatient hospitalizations. This aligns with the intent of the MVP to focus on kidney disease. We also propose the TPCC measure because it is a broad measure that includes nephrologists and aligns with the similarly broad quality measures included in the MVP. Two episode-based cost measures are currently under development for chronic kidney disease (CKD) and end-stage renal disease (ESRD). The measures would focus on outpatient management of these conditions. The measures could be considered for future inclusion in this MVP.

TABLE A.2: Optimal Care for Kidney Health MVP

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Optimal Care for Kidney Health MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(**) Q110:** Preventive Care and Screening: Influenza Immunization (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(**) Q111:** Pneumococcal Vaccination Status for Older Adults (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) **(^) TBD:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High) **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice Improvements for Bilateral Exchange of Patient Information (Medium) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium)	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **Total Per Capita Cost (TPCC)**

	IA_PSPA_16: Use of decision support and standardized treatment protocols (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review	

A.3 Optimal Care for Patients with Episodic Neurological Conditions MVP

The proposed Optimal Care for Patients with Episodic Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from episodic neurological conditions. This proposed MVP would be most applicable to clinicians who treat patients within the practice of neurology.

Quality Measures

We propose to include four MIPS quality measures and six QCDR measures within the quality component of this MVP, which focus on a variety of neurological conditions that may impact patient health. We reviewed the MIPS quality measure inventory and believe the following quality measures would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with episodic neurological conditions:

- Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: This MIPS quality measure assesses patients, that are diagnosed with epilepsy and are of child-bearing age, to ensure they receive counseling regarding how the treatment of epilepsy may affect contraception and pregnancy.
- Q419: Overuse of Imaging for the Evaluation of Primary Headache: This MIPS quality measure assesses overuse of the head (CT or MRI) for the evaluation of primary headache.
- AAN5: Medication Prescribed for Acute Migraine Attack: This QCDR measure assesses pediatric and adult patients diagnosed with migraine that were prescribed a guideline recommended or FDA approved/cleared treatment for acute migraine attacks.
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions: This QCDR measure evaluates performance outcomes for patients with neurologic conditions. The outcomes from these assessments should reflect an improvement or maintenance of a patient's perceived quality of life. This measure includes patients diagnosed with the following neurologic conditions: amyotrophic lateral sclerosis, attention deficit disorders, autism, cerebral palsy, cognitive impairment and related dementias, developmental delays, headache and migraine, movement disorders, multiple sclerosis, muscular dystrophy, neoplasms of brain and spine, polyneuropathy, seizure and epilepsy, stroke, tic disorders, vertigo, and related neuro-otology disorders.
- AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy: This QCDR measure assesses for patients that had referrals or a discussion of evaluation at a comprehensive epilepsy care center.
- AAN30: Migraine Preventive Therapy Management: This QCDR measure assesses pediatric and adult patients diagnosed with migraine, that occur with a frequency is greater than or equal to 6 days per month/4 attacks per month, receive evidence-based preventive migraine therapy, including therapies prescribed by another clinician.
- AAN31: Acute Treatment Prescribed for Cluster Headache: This QCDR measure ensures patients diagnosed with cluster headache were prescribed an acute treatment, including treatments prescribed by a different clinician.
- AAN32: Preventive Treatment Prescribed for Cluster Headache: This QCDR measure ensures patients diagnosed with cluster headache were prescribed short-term and/or long-term preventive treatment, including treatments prescribed by a different clinician.

In conjunction with the aforementioned neurological measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to neurological conditions. The quality measures below encourage advance care planning and documentation of current medications, which capture the patient's voice and supports safety for patients that are experiencing episodic neurological conditions:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_24: Financial Navigation Program
- IA_BMH_4: Depression screening
- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access

- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

Within the cost component of this MVP, we propose to include the Medicare Spending Per Beneficiary (MSPB) Clinician measure because it applies to clinicians providing care in inpatient hospitals, including care for patients with neurological conditions. This is in line with the intent of the MVP. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.3: Optimal Care for Patients with Episodic Neurological Conditions MVP

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Optimal Care for Patients with Episodic Neurological Conditions MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*)(!) **Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) (!) **Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs Specifications) (#) **AAN5:** Medication Prescribed for Acute Migraine Attack (Collection Type: QCDR) (#)(!)(!!) **AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) (#) **AAN29:** Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy (Collection Type: QCDR) (#) **AAN30:** Migraine Preventive Therapy Management (Collection Type: QCDR) (#) **AAN31**: Acute Treatment Prescribed for Cluster Headache (Collection Type: QCDR) (#) **AAN32:** Preventive Treatment Prescribed for Cluster Headache (Collection Type: QCDR)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

	IA_PSPA_21: Implementation of fall screening and assessment programs (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review	

A.4 Supportive Care for Neurodegenerative Conditions MVP

The proposed Supportive Care for Neurodegenerative Conditions MVP focuses on the clinical theme of promoting quality care for patients with cognitive-based neurological disorders such as dementia, Parkinson's Disease (PD), and Amyotrophic Lateral Sclerosis (ALS). This proposed MVP would be most applicable to clinicians who treat patients with cognitive-based neurological disorders within the practice of neurology.

Quality Measures

We propose to include ten MIPS quality measures and three QCDR measures within the quality component of this MVP, which focus on a variety of cognitive-based neurological disorders that may impact patient health. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with cognitive-based neurological disorders:

- Q281: Dementia: Cognitive Assessment: This MIPS quality measure evaluates for the performance of a cognitive assessment for patients diagnosed with dementia.
- Q282: Dementia: Functional Status Assessment: This MIPS quality measure evaluates for the performance of a functional status assessment for patients diagnosed with dementia.
- Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure assesses for the discussion of safety concerns with either the patients diagnosed with dementia or their caregivers. There are two domains of safety that should be addressed to meet performance of the measure which include dangerousness to self or others and environmental risks. If a risk is discovered, it is anticipated that the clinician would document mitigation recommendations to promote safety outcomes for these patients.
- Q288: Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure ensures clinician communication of education on dementia disease management and health behavior with the added support of referrals to additional support resources for patients diagnosed with dementia and their caregivers.
- Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease: This MIPS quality measure evaluates if patients diagnosed with Parkinson's Disease receive an assessment for depression, anxiety, apathy, and psychosis.
- Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease: This MIPS quality measure assesses for the performance of a cognitive impairment or dysfunction for patients diagnosed with Parkinson's Disease.
- Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease: This MIPS quality measure evaluates if patients, diagnosed with Parkinson's Disease, receive referrals for physical, occupational, speech, or recreational therapy.
- Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: This MIPS quality measure assesses patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) to ensure they are offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice).
- AAN9: Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease: This QCDR measure evaluates if patients diagnosed with Parkinson's Disease are queried about symptoms of autonomic dysfunction and if screened positive for autonomic dysfunction receive appropriate follow-up.
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions: This QCDR measure evaluates performance outcomes for patients with neurologic conditions. The outcomes from these assessments should reflect an improvement or maintenance of a patient's perceived quality of life. This measure includes patients diagnosed with the following neurologic conditions: amyotrophic lateral sclerosis, attention deficit disorders, autism, cerebral palsy, cognitive impairment and related dementias, developmental delays, headache and migraine, movement disorders, multiple sclerosis, muscular dystrophy, neoplasms of brain and spine, polyneuropathy, seizure and epilepsy, stroke, tic disorders, vertigo, and related neuro-otology disorders.
- AAN34: Patient reported falls and plan of care: This QCDR measure assesses that patients with the diagnosis of a movement disorder, or caregivers as appropriate, have a plan of care in the instance a fall is reported. For this measure, a movement disorder includes multiple sclerosis, a neuromuscular disorder, dementia, or stroke.

In conjunction with the aforementioned cognitive-based neurological measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to cognitive-based neurological disorders. The quality measures below address advance care planning and documentation of current medications, which support the capture of the patient's voice and safety for patients that are experiencing cognitive-based neurological disorders:

- Q047: Advance Care Plan: This MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q238: Use of High-Risk Medications in Older Adults: This MIPS quality measure supports patient safety by assessing for the use of high-risk medications.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_24: Financial Navigation Program
- IA_BMH_4: Depression screening
- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

Within the cost component of this MVP, we propose to include the Medicare Spending Per Beneficiary (MSPB) Clinician measure because it applies to clinicians providing care in inpatient hospitals, including care for patients with cognitive-based neurological conditions. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.4: Supportive Care for Neurodegenerative Conditions MVP

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the Supportive Care for Neurodegenerative Conditions MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **(!) Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(*)(!) Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **(#) AAN9:** Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (Collection Type: QCDR) **(#)(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **(#)(!)(!!) AAN34:** Patient reported falls and plan of care (Collection Type: QCDR)	**(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review

A.5 Promoting Wellness MVP

The proposed Promoting Wellness MVP focuses on the clinical theme of promoting quality care for patients. This proposed MVP would be most applicable to clinicians who treat patients within the practice of preventive medicine, internal medicine, family medicine, and geriatrics.

Quality Measures

We propose to include fourteen MIPS quality measures within the quality component of this MVP, which promote general physical and mental wellness within patients. Preventive care is vital to reducing risk of diseases, disabilities, and death; however, many people within the United States still do not receive the recommended preventive screenings and services. The quality measures below include assessments for appropriate immunization status in addition to representing screenings for cancers, sexually transmitted infections, and osteoporosis, all of which drive quality care for preventive medicine for a broad patient population. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed

within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing preventive care:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women, 65-85 years of age, who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.
- Q112: Breast Cancer Screening: This MIPS quality measure ensures women have a mammogram to screen and for breast cancer.
- Q113: Colorectal Cancer Screening: This MIPS quality measure ensures patients have received appropriate screening for colorectal cancer.
- Q309: Cervical Cancer Screening: This MIPS quality measure assesses women to determine if they were screened for cervical cancer.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure requires that patients have received a one-time screening for hepatitis C virus (HCV) infection.
- Q475: HIV Screening: This MIPS quality measure ensures patients received a one-time test for HIV.
- TBD: Adult Immunization Status: This MIPS quality measure ensures patients are assessed for and/or receive the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines, as recommended.

In conjunction with the aforementioned promoting wellness measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to promoting wellness. The quality measures below address preventive care and screening by supporting the assessment of body mass index, mental health, tobacco, and alcohol use. Additionally, this MVP includes two quality measures that capture the patient's voice and support clinicians' care goals for optimizing the patient's experience while receiving care for comprehensive health wellness:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, with a BMI documented and who had a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use and if the patient is screened positive for tobacco use then they should receive tobacco cessation intervention.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey would provide direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients, aged 18 years and older, for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. If the patient is screened positive for unhealthy alcohol use, then they should receive brief counseling.
- Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM): This MIPS quality measure evaluates the high value aspects of primary care based on a patient's relationship with the clinician or practice and allows patients the ability to communicate their perspective of the quality of care received to their clinicians and/or care team.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include fourteen improvement activities that reflect actions and processes undertaken by clinicians who provide chronic disease-preventive care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing chronic disease management or preventive care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_BMH_9: Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients

- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

Within the cost component of this MVP, we propose to include the Total Per Capita Cost (TPCC) measure because it captures the total costs of care. This broad cost measure aligns with the MVP scope to include a range of measures and activities to promote wellness across different clinical topics. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future.

TABLE A.5: Promoting Wellness MVP

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Promoting Wellness MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(*)(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **(*) Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **Q475:** HIV Screening	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_BMH_9:** Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium)	**Total Per Capita Cost (TPCC)**

(Collection Type: eCQM Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) (^) TBD: Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**(*) IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes, or other practice improvement processes (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review	

Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Table B.1: Advancing Care for Heart Disease MVP

Table B.1 represents the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (86 FR 66014 through 66015) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Advancing Care for Heart Disease MVP to include cardiovascular care in general as well as cardiology subspecialists in order to capture a more complete picture of quality care for patients who are at risk of or who have heart disease. Therefore, we are proposing to expand the Advancing Care for Heart Disease MVP to include six additional quality measures that encompass the clinical care of electrophysiology, heart failure, and interventionalist subspecialists:

- Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: This MIPS quality measure assesses patients with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism.
- Q377: Functional Status Assessments for Heart Failure: This MIPS quality measure assesses patients with heart failure who completed initial and follow-up patient-reported functional status assessments.
- Q392: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation: This MIPS quality measure assesses the rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation.
- Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision: This MIPS quality measure assesses the infection rate following CIED device implantation, replacement, or revision.
- TBD: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System: This MIPS quality measure assesses annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients with heart failure (HF) or cardiomyopathy.

In conjunction with the aforementioned heart disease measures, we propose to include the following broadly applicable MIPS quality measure that is relevant to patients receiving cardiovascular care. The quality measure below addresses preventive care and screening of patients for depression:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan discussed for those patients who screen positive.

Also, we are proposing to add one improvement activity, IA_PM_13: Chronic care and preventative care management for empaneled patients and remove two improvement activities, IA_EPA_4: Additional improvements in access as a result of QIN/QIO TA and IA_PSPA_30: PCI Bleeding Campaign from this MVP. The proposed changes specific to IA_PM_13 and IA_EPA_4 are in response to public comments we received in the 2022 PFS final rule (86 FR 66012). One commenter believed IA_PM_13 was designed to directly address patients assigned to care teams for the purpose of population health management and encourages the adoption of practices and protocols that are essential in high-quality care for chronic diseases. After consideration, we agree that IA_PM_13 is a better choice for this MVP than IA_EPA_4 because of IA_PM_13's direct focus on preventive care and patient empanelment. The commenter also suggested the removal of IA_EPA_4 because the commenter believed it has minimal specificity for the MVP. After consideration, we agree making this change would best provide sufficient provider choice while not including an overwhelming number of improvement activity options in this MVP. The proposal to remove IA_PSPA_30 is being made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of this proposed rule and is contingent on those proposals being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we are proposing to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

This MVP was previously adopted to be most applicable to clinicians who practice in the following specialties:

- Cardiology
- Internal Medicine
- Family Medicine

With the proposed modifications, these additional clinicians who practice in the following specialties may want to consider reporting this MVP:

- Electrophysiology
- Heart Failure Specialists
- Interventionalists

The proposed additions are identified with a plus sign (+) before the quality measure and improvement activity ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(*) **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*) **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*) **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*) **Q128**: Preventive care and screening: Body Mass Index (BMI) screening and follow-up plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) (+)(*) **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) (+)(!!) **Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) (+)(!!) **Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) (*)(!!) **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications)	**IA_BE_12:** Use of evidence-based tools to support shared decision making (Medium) **IA_BE_15:** Engagement of Patients, Families, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) (~) **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) (*)(~) **IA_CC_14:** Practice Improvements that Engage Community Resources to Support Patient Health Goals (High) (+)(%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (+) **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) (~) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) (*)(~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**Elective Outpatient Percutaneous Coronary Intervention** **ST Elevation Myocardial Infarction with Percutaneous Coronary Intervention** **Total Per Capita Cost (TPCC)**

(+)(^)(!!) **TBD:** Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims)		
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

Table B.2: Optimizing Chronic Disease Management MVP

Table B.2 represents the measures and activities that were finalized within the Optimizing Chronic Disease Management MVP in (86 FR 66021 through 66022) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Optimizing Chronic Disease Management MVP to include Q321: CAHPS for MIPS Clinician/Group Survey. While this MVP already includes a patient experience measure, Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure, we are proposing to add an additional option for assessing the patient experience. The addition of the CAHPS for MIPS Clinician/Group survey measure to this MVP would provide primary care clinicians more flexibility when choosing a patient experience evaluation and allows for the use of a survey vendor. Capturing the patient experience is a priority of the MIPS program and this proposed addition would allow clinicians to choose a patient experience measure that best fits their clinical workflow.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed additions are identified with a plus sign (+) before the quality measure ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(*) Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q047**: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q107:** Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications) **(*) Q118**: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQMs Specifications) **(*) Q119**: Diabetes: Medical Attention for Nephropathy (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236**: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+)(*)(!) Q321**: CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(!!) Q398:** Optimal Asthma Control (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3**: Promote use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_22**: Improved practices that engage patients pre-visit (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) **(*) IA_CC_13**: Practice improvements for bilateral exchange of patient information (Medium) **(*)(~) IA_CC_14:** Practice Improvements that Engage Community Resources to Support Patient Health Goals (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients	**Total Per Capita Cost (TPCC)**

	(Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **(*) IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

Table B.3: Advancing Rheumatology Patient Care MVP

Table B.3 represents the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (86 FR 66002 through 66003) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Advancing Rheumatology Patient Care MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program. This proposal is being made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of this proposed rule and is contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we are proposing to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

Also, we are proposing to remove improvement activity, IA_BMH_4: Depression screening and add Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, which is a broadly applicable quality measure that encompasses the same concept and assesses an important aspect of care for patients with chronic diseases. We believe Q134 is better suited than IA_BMH_4 for this MVP, because it ensures that all patients without a history of depression or bipolar disorder are being screened for depression and a follow-up plan is discussed if the patient screens positive. Q134 supports depression screening for a more general patient population, allowing early detection and treatment. Additionally, we believe this clinician patient interaction is an important aspect of care for this patient population because depression is a common comorbidity in patients with various rheumatic diseases. Therefore, we propose to add measure Q134 as it ensures depression screening for each patient.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed additions are identified with a plus sign (+) before the quality measure and improvement activity ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(*)(**) **Q111:** Pneumococcal Vaccination Status for Older Adults (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*) **Q176:** Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (Collection Type: QCDR) (!!) **ACR14:** Gout Serum Urate Target (Collection Type: QCDR) (!) **ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	(~) **IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) (~) **IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BMH_2:** Tobacco use (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (IIigh) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (+)(%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR **(^)** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

TABLE B.4: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.4 represents the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (86 FR 66024 through 66025) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program and IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes. These proposals are being made in conjunction with our proposals to remove these improvement activities from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of this proposed rule and is contingent on those proposals being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we are proposing to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed additions are identified with a plus sign (+) before the improvement activity ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(*)(!) **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications) **Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Collection Type: MIPS CQMs Specifications) (*)(!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (!) **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) (!) **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) (!) **ACEP21:** Coagulation Studies in Patients Presenting with Chest Pain with No Coagulopathy or Bleeding (Collection Type: QCDR) (!!) **ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) (!) **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) (!) **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) (*)(~) **IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) (+)(%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (*)(~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium) (*) **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information	

(Collection Type: Administrative Claims)	Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

TABLE B.5: Improving Care for Lower Extremity Joint Repair MVP

Table B.5 represents the measures and activities that were finalized within the Improving Care for Lower Extremity Joint Repair MVP in (86 FR 66027 through 66028) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Improving Care for Lower Extremity Joint Repair MVP to remove IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program. This proposal is being made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of this proposed rule and is contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we are proposing to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed additions are identified with a plus sign (+) before the improvement activity ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_15:** PSH Care Coordination (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing **(*)** Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information	

(Collection Type: Administrative Claims)	Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

TABLE B.6: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.6 represents the measures and activities that were finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP in (86 FR 66030 through 66031) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

We are proposing to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to remove IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes. This proposal is being made in conjunction with our proposal to remove this improvement activity from the MIPS Improvement Activity Inventory as discussed in Appendix 2 of this proposed rule and is contingent on that proposal being finalized as proposed. In addition, for the reasons stated earlier in this Appendix 3, we are proposing to add IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation to this MVP.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed additions are identified with a plus sign (+) before the improvement activity ID # and before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(!!) Q404: Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) **(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) **(!) AQI69:** Intraoperative Antibiotic Redosing (Collection Type: QCDR)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_15:** PSH Care Coordination (High) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) **(+)(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(*)(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review

TABLE B.7: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.7 represents the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in (86 FR 66007 through 66008) with modifications proposed for the CY 2023 performance period/2025 MIPS payment year and future years.

For the reasons stated earlier in this Appendix 3, we propose to add the Promoting Interoperability performance category ONC Direct Review attestation requirement described under § 414.1375(b)(3) to this MVP.

The proposed addition is identified with a plus sign (+) before the Promoting Interoperability title in this table.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications) **(!!) Q409:** Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications)	**(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model	**Intracranial Hemorrhage or Cerebral Infarction**

(!!) Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications)	**IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing (*) Query of the Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR (^) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT (+) ONC Direct Review	

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; FY 2023 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update and Quality Reporting—Request for Information; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1769–F]

RIN 0938–AU80

Medicare Program; FY 2023 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update and Quality Reporting—Request for Information

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. This final rule establishes a permanent mitigation policy to smooth the impact of year-to-year changes in IPF payments related to decreases in the IPF wage index. In addition, this final rule includes responses to public comments received on the results of the data analysis of the IPF Prospective Payment System (PPS) adjustments. These changes will be effective for IPF discharges occurring during the Fiscal Year (FY) beginning October 1, 2022, through September 30, 2023 (FY 2023). Lastly, this final rule includes public comments received in response to requests for information that appeared in the FY 2023 IPF PPS proposed rule.

DATES: Effective October 1, 2022.

FOR FURTHER INFORMATION CONTACT: The IPF Payment Policy mailbox at *IPFPaymentPolicy@cms.hhs.gov* for general information.

Mollie Knight (410) 786–7948 or Eric Laib (410) 786–9759, for information regarding the market basket update or the labor-related share.

Nick Brock (410) 786–5148 or Theresa Bean (410) 786–2287, for information regarding the regulatory impact analysis.

Lauren Lowenstein (410) 786–4507, for information regarding the inpatient psychiatric facilities quality reporting program.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this final rule summarizes the FY 2023 IPF PPS payment rates, outlier threshold, cost of living adjustment factors (COLA) for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, the B Addenda to this final rule shows the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, the FY 2023 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. The A and B Addenda are available online at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

Tables setting forth the FY 2023 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the FY 2023 Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the internet, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html.*

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during Fiscal Year (FY) 2023 beginning October 1, 2022 through September 30, 2023. This final rule establishes a permanent mitigation policy to smooth the impact of year-to-year changes in IPF payments related to changes in the IPF wage index. In addition, this final rule includes responses to public comments received on the results of the data analysis of the IPF Prospective Payment System (PPS) adjustments. Lastly, this final rule includes public comments received in response to requests for information that appeared in the FY 2023 IPF PPS proposed rule.

B. Summary of the Major Provisions

1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)

For the IPF PPS, we are finalizing our proposal to—

- Establish a permanent mitigation policy in order to smooth the impact of year-to-year changes in IPF payments related to decreases to the IPF wage index.
- Adjust the 2016-based IPF market basket update (4.1 percent) for economy-wide productivity (0.3 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), resulting in a final IPF payment rate update of 3.8 percent for FY 2023.
- *Make technical rate setting changes:* The IPF PPS payment rates will be adjusted annually for inflation, as well as statutory and other policy factors. This final rule updates:

++ The IPF PPS Federal per diem base rate from $832.94 to $865.63.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to $848.95.

++ The ECT payment per treatment from $358.60 to $372.67.

++ The ECT payment per treatment for providers who failed to report quality data to $365.49.

++ The labor-related share from 77.2 percent to 77.4 percent.

++ The wage index budget-neutrality factor to 1.0012.

++ The fixed dollar loss threshold amount from $16,040 to $24,630 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

We did not propose any changes to the IPFQR Program and are not finalizing any changes to the IPFQR Program. We did receive many comments requesting that we add a patient experience of care measure to the IPFQR Program. Additionally, one commenter recommended that CMS adopt a patient and workforce safety measure for the IPF setting. We also received several comments recommending that CMS adopt a value-based purchasing program for the IPF setting. Finally, one commenter provided input about depression screening instruments for CMS's ongoing work to develop a measure of improvement of depression symptoms. We appreciate these comments but note that they fall outside the scope of this rulemaking. We will consider all these comments as we continue to evolve the IPFQR Program in the future.

We also included a request for information (RFI) on the Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs. Feedback provided will inform future efforts in all CMS Quality programs and, as applicable, may be introduced in the IPFQR as future RFIs or proposals.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2023 IPF PPS payment update	The overall economic impact of this final rule is an estimated $90 million in increased payments to IPFs during FY 2023.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem payment perspective system (PPS) for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. ''Excluded psychiatric unit'' means a psychiatric unit of an acute care hospital or of a Critical Access Hospital (CAH), which is excluded from payment under the Inpatient Prospective Payment System (IPPS) or CAH payment system, respectively. These excluded psychiatric units will be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as ''the Affordable Care Act'') added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled ''Reference to Establishment and Implementation of System,'' refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY.

Section 1886(s)(2)(A)(ii) of the Act required the application of an ''other adjustment'' that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 IPF PPS final rule, for the RY beginning in 2019, section 1886(s)(3)(E) of the Act required that the other adjustment reduction be equal to 0.75 percentage point; that was the final year the statute required the application of this adjustment. Because FY 2021 was a RY beginning in 2020, FY 2021 was the first year section 1886(s)(2)(A)(ii) did not apply since its enactment.

Sections 1886(s)(4)(A) through (D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard Federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not consider such reduction in computing the payment amount for a subsequent RY. Additional information about the specifics of the current IPFQR Program is available in the FY 2020 IPF PPS and Quality Reporting Updates for FY Beginning October 1, 2019 final rule (84 FR 38459 through 38468).

To implement and periodically update these provisions, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, see the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/*.

B. Overview of the IPF PPS

On November 15, 2004, we published the IPF PPS final rule in the **Federal Register** (69 FR 66922). The November 2004 IPF PPS final rule established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The November 2004 IPF PPS final rule set forth the Federal per diem base rate for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences; with statistical significance defined as p less than 0.05. A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities, as well as adjustments to reflect higher per diem costs at the beginning of a

patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS has additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. In the November 2004 IPF PPS final rule (69 FR 66922), we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

In developing the IPF PPS, and to ensure that the IPF PPS can account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and our November 15, 2004 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the November 2004 IPF final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)'' (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1st. When proposing changes in IPF payment policy, a proposed rule is issued in the spring, and the final rule in the summer to be effective on October 1st. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428.

The most recent IPF PPS annual update was published in a final rule on August 4, 2021 in the **Federal Register** titled, ''Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022)'' (86 FR 42608), which updated the IPF PPS payment rates for FY 2022. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2021 IPF PPS Rate Update final rule (85 FR 47042) in accordance with our established policies.

III. Analysis of and Responses to Public Comments

We received 396 public comments, 27 of which pertained to proposed IPF PPS payment policies, 20 of which pertained to the request for comments on addressing healthcare disparities and advancing healthcare equity in the IPFQR Program, and the remainder were seeking to encourage the addition of a patient experience of care measure into the IPFQR Program. Comments were from health systems, national and state-level provider and patient advocacy organizations, MedPAC, and individuals. We reviewed each comment and grouped related comments, after which we placed them in categories based on subject matter or section(s) of the regulation affected. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

IV. Provisions of the FY 2023 IPF PPS Final Rule and Responses to Comments

A. FY 2023 Market Basket Update and Productivity Adjustment for the IPF PPS

1. Background

Originally, the input price index that was used to develop the IPF PPS was the ''Excluded Hospital with Capital'' market basket. This market basket was based on 1997 Medicare cost reports for Medicare participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although ''market basket'' technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. The term market basket as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the IPF market basket in the FY 2020 IPF PPS rule, where we adopted a 2016-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer readers to the FY 2020 IPF PPS final rule for a detailed discussion of the 2016-based IPF PPS market basket and its development (84 FR 38426 through 38447). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. FY 2023 IPF Market Basket Update

For FY 2023 (beginning October 1, 2022 and ending September 30, 2023), we proposed to update the IPF PPS payments by a market basket increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Consistent with historical practice, we proposed to estimate the market basket update for the IPF PPS based on the most recent forecast available at the time of rulemaking from IHS Global Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and productivity adjustment. For the proposed rule, based on IGI's fourth quarter 2021 forecast with historical data through the third quarter of 2021, the proposed 2016-based IPF market basket increase factor for FY 2023 was 3.1 percent.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary of the Department of Health and Human Services (the Secretary) shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned previously, the data and methods are unchanged. We refer readers to *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, in the FY 2022 IPF final rule (86 FR 42611), we noted that effective with FY 2022 and forward, CMS changed the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

For the FY 2023 IPF PPS proposed rule, based on IGI's fourth quarter 2021 forecast, the proposed productivity adjustment for FY 2023 (the 10-year moving average growth in TFP for the period ending FY 2023) was projected to be 0.4 percent. Accordingly, we proposed to reduce the proposed 3.1 percent IPF market basket update by this proposed 0.4 percentage point productivity adjustment, as mandated by the Act. This resulted in a proposed FY 2023 IPF PPS payment rate update of 2.7 percent (3.1 − 0.4 = 2.7). We also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2023 IPF market basket update and productivity adjustment for the final rule.

Comment: Commenters appreciated the positive proposed update to the IPF market basket for FY 2023; however, many commenters expressed concern that the proposed 2.7 percent market basket update (reflecting a 3.1 percent market basket update less 0.4 percentage point productivity adjustment) was inadequate, particularly noting the historically high inflation rates. The commenters acknowledged that CMS will refresh the market basket update in the final rule but were deeply concerned the revised update would continue to be insufficient relative to input cost inflation. They stated that hospitals on the front lines of the ''coronavirus disease 2019'' (abbreviated ''COVID–19'') Public Health Emergency (PHE) during the past 2 years continue to weather a number of market pressures such as labor shortages (which have led to use of more contract labor) and supply chain issues. One commenter stated that the rate update does not account for the many issues that their system encounters, including higher acuity patients, additional staffing to meet acuity needs and care for underserved patients. Another commenter stated that unlike many of the other hospitals and providers, IPFs did not receive any targeted funding allocation from the Provider Relief Fund to address their increased costs as well as the increased need for mental healthcare and addiction treatment during this pandemic.

Many commenters believe CMS's current methodology for updating the market basket is ill-suited to adequately adjust Medicare payments in a highly inflationary environment. Therefore, they recommended that CMS consider other methods and data sources to calculate the final rule market basket update and an alternative approach to better align the market basket increases with increases in cost to treat patients, including using the authority under section 1886(s) of the Act to further increase IPF rates to better adjust FY 2023 payments to IPFs to account for inflation.

Response: We believe the 2016-based IPF market basket increase adequately reflects the average change in the price of goods and services hospitals purchase in order to provide IPF medical services, and is appropriate to use as the IPF payment update factor. As described in the FY 2020 IPF final rule (84 FR 38426 through 38447), the IPF market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the IPF market basket update would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices), but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses. We note that cost changes (that is, the product of price and quantities) would only be reflected when a market basket is rebased and the base year weights are updated to a more recent time period.

We agree with the commenters that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. Based on IGI's fourth quarter 2021 forecast with historical data through the third quarter of 2021, the proposed 2016-based IPF market basket update for FY 2023 was 3.1 percent, reflecting forecasted compensation price growth of 3.5 percent (by comparison, compensation price growth in the IPF market basket averaged 2.2 percent from 2012–2021). In the FY 2023 IPF PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2023 IPF market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the United States economy and expected price inflation for FY 2023 for IPFs. Based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022, the final FY 2023 IPF market basket update is 4.1 percent (reflecting forecasted compensation price growth of 4.5 percent) and the final FY 2023 productivity adjustment is 0.3 percentage point. Therefore, for FY 2023, the final IPF productivity-adjusted market basket update is 3.8 percent (4.1 percent less 0.3 percentage point), compared to the proposed 2.7 percent productivity-adjusted market basket update. We note that the final FY 2023 IPF market basket growth rate of 4.1 percent would be the highest market basket update we have implemented in a final rule since the beginning of the IPF PPS.

With respect to the comment about the lack of a targeted funding allocation for IPFs from the Provider Relief Fund, we do not agree with the commenter and note that IPFs were included in the types of eligible specialty hospitals for rural targeted distribution payments.[1]

Lastly, regarding commenters' request that CMS consider other methods and data sources to calculate the final rule market basket update, including the authority under section 1886(s) of the Act, while we generally agree that the Secretary has broad authority under the statute to establish the methodology for updating the IPF PPS base rate, our longstanding policy since the inception of the IPF PPS has been to update IPF PPS payments based on an appropriate market basket. As discussed earlier in this section of this final rule, the market basket used to update IPF PPS payments has been rebased and revised over the history of the IPF PPS to reflect more recent data on IPF cost structures, and we believe it continues to appropriately reflect IPF cost structures. We did not propose to use other methods or data sources to calculate the final market basket update for FY 2023, and we are not finalizing such an approach for this final rule. Consistent with our proposal, we have used more recent data to calculate a final IPF productivity-adjusted market basket update of 3.8 percent for FY 2023.

Comment: One commenter stated that the market basket updates in FY 2021 and FY 2022 are currently estimated to underinflate the base IPF rate by 1.9 percent, which means the base rate for FY 2023 is 1.9 percent too low.

Response: The IPF market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the FY 2023 market basket update in this final rule reflects historical data through the first quarter of CY 2022 and forecasted data through the third quarter of CY 2023. While there is no precedent to adjust for market basket forecast error in the IPF payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. This was the case for the FY 2020 IPF forecast error, which was –0.7 percentage point, and the FY 2021 IPF forecast error, which was +0.7 percentage point; FY 2022 historical data is not yet available to calculate a forecast error for FY 2022. Regarding the comment that the FY 2023 IPF base rate is 1.9 percent too low, we disagree with this assertion as it does not consider years in which the base rates may have been overinflated. For this final rule, we have incorporated more recent historical data and forecasts to capture the price and wage pressures facing IPFs. We believe it is the best available projection of inflation to determine the applicable percentage increase for the IPF payments in FY 2023.

Comment: One commenter stated that with the significant increase in inflation that has already taken place in 2022, they did not support using 2021 historical data to set the FY 2023 rates. The commenter stated that an additional increase should be added to the 2021 historical data to help offset the significant increased costs that providers are currently experiencing.

Response: In determining the FY 2023 IPF market basket update of 4.1 percent, a combination of observed and forecasted trends were used. Actual experience is incorporated through first quarter 2022, and forecasted trends through the remaining quarters of FY 2022 and all of FY 2023. Likewise, the FY 2024 market basket update would reflect not only historical data through 2022 but also forecasted trends through FY 2024.

Comment: Several commenters disagreed with the assumptions underpinning the productivity adjustment. They stated that the productivity adjustment to the market basket update assumes IPFs can increase overall productivity at the same rate as increases in the broader economy, and referenced CMS Office of the Actuary analysis that compares private non-farm total factor productivity growth measure and a hospital-specific measure (*https://www.cms.gov/files/document/productivity-memo.pdf*). The commenters stated that IPF services are highly labor-intensive, and therefore, IPFs cannot improve productivity using strategies like offshoring or automation that are commonly deployed in other sectors of the economy. The commenters claimed that during the PHE productivity fell as result of having to use temporary staffing due to labor shortages.

In addition, the commenters stated that although CMS is required by statute to implement a productivity adjustment to the market basket update, they requested that CMS work with the Congress to permanently eliminate the productivity adjustment. Furthermore, the commenters recommended that CMS use its Section 1135 waiver authority to remove the productivity adjustment for any FY that was covered under the PHE determination (that is, 2020, 2021, and 2022) from the calculation of market basket for FY 2023 and any year thereafter that the PHE continues.

Response: Section 1886(s)(2)(A)(i) of the Act requires the application of a productivity adjustment to the IPF PPS market basket increase factor. As required by statute, the FY 2023 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2023. Regarding the suggestion that CMS consider section 1135 waiver authority to suspend application of the productivity adjustment, such authority is unavailable in this circumstance. Section 1135 of the Act authorizes the Secretary to waive or modify only those statutory provisions and regulations described at section 1135(b) of the Act, such as conditions of participation or providers' regulatory deadlines. Payment requirements, such as the application of the productivity adjustment under the IPF PPS, are not one of the types of requirements set out under this subsection.

Final Decision: After consideration of the comments we received, we are finalizing a FY 2023 IPF productivity-adjusted market basket update equal to 3.8 percent based on the more recent data available. This 3.8 percent update is based on a more recent forecast of the FY 2023 IPF market basket update of 4.1 percent reduced by a statutorily required productivity adjustment of 0.3 percentage point.

3. FY 2023 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2016-based IPF market basket, we proposed to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee

[1] *https://www.hrsa.gov/sites/default/files/hrsa/provider-relief/provider-relief-fund-faq-complete.pdf.*

Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related relative importance from the 2016-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2016-based IPF labor-related share, see the FY 2020 IPF PPS final rule (84 FR 38445 through 38447).

The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2016) and FY 2023. Based on IGI's fourth quarter 2021 forecast of the 2016-based IPF market basket, the sum of the FY 2023 relative importance moving average of Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services was 74.4 percent. We proposed, consistent with prior rulemaking, that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 6.6 percent of the 2016-based IPF market basket for FY 2023, we proposed to take 46 percent of 6.6 percent to determine a labor-related share of Capital-Related costs for FY 2023 of 3.0 percent. Therefore, we proposed a total labor-related share for FY 2023 of 77.4 percent (the sum of 74.4 percent for the labor-related share of operating costs and 3.0 percent for the labor-related share of Capital-Related costs). We also proposed that if more recent data became available, we would use such data, if appropriate to determine the FY 2023 labor-related share for the final rule. For more information on the labor-related share and its calculation, we refer readers to the FY 2020 IPF PPS final rule (84 FR 38445 through 38447).

We invited public comments on the proposed labor-related share for FY 2023.

Comment: One commenter did not support CMS's proposal to increase the labor-related share from 77.2 percent in FY 2022 to 77.4 percent in FY 2023, stating that any increase to the labor-related share penalizes facilities that have a wage index less than 1.0. The commenter also stated that there is a growing disparity between high-wage and low-wage states that harms hospitals in many rural and underserved communities. In addition, the commenter stated that they believe CMS should consider excluding the labor portion of capital related costs for FY 2023 and going forward.

Response: We proposed to use the FY 2023 relative importance values for the labor-related cost categories from the 2016-based IPF market basket because it accounts for more recent data regarding price pressures and cost structure of IPFs. This methodology is consistent with the determination of the labor-related share since the implementation of the IPF PPS in 2007. The labor-related cost categories reflect IPF costs that are related to, influenced by, or vary with the local labor market, which would include a portion of the capital-related costs. Therefore, we disagree with the commenter that we should exclude the labor portion of capital-related costs for FY 2023 and going forward. As stated in the FY 2023 IPF proposed rule, we also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2023 labor-related share for the final rule. Based on IHS Global Inc.'s second quarter 2022 forecast with historical data through the first quarter of 2022, the FY 2023 labor-related share for the final rule is 77.4 percent, unchanged from the proposed rule.

Final Decision: After consideration of the comments we received, we are finalizing a FY 2023 labor-related share equal to 77.4 percent based on the latest available IGI forecast.

Table 1 shows the FY 2023 labor-related share and the final FY 2022 labor-related share using the 2016-based IPF market basket relative importance.

TABLE 1: FY 2023 IPF Labor-Related Share and FY 2022 IPF Labor-Related Share

	Relative importance, labor-related share FY 2023[1]	Relative importance, labor-related share FY 2022[2]
Wages and Salaries	53.2	52.8
Employee Benefits	13.5	13.6
Professional Fees: Labor-related	4.3	4.3
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair	1.3	1.3
All Other Labor-related Services	1.5	1.5
Subtotal	**74.4**	**74.1**
Labor-related portion of Capital-Related (.46)	3.0	3.1
Total Labor-Related Share	**77.4**	**77.2**

1. Based on the 2nd quarter 2022 IHS Global Inc. forecast of the 2016-based IPF market basket.
2. Based on the 2nd quarter 2021 IHS Global Inc. forecast of the 2016-based IPF market basket.

B. Updates to the IPF PPS Rates for FY Beginning October 1, 2022

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost

appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget-Neutral Federal Per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, had to be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. The information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be $575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral Federal per diem base rate and the electroconvulsive therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html.*

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries in order to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*) There were no changes to the ECT procedure codes used on IPF claims as a result of the final update to the ICD–10–PCS code set for FY 2023. Addendum B to this final rule shows the ECT procedure codes for FY 2023 and is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

2. Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy Payment per Treatment

The current (FY 2022) Federal per diem base rate is $832.94 and the ECT payment per treatment is $358.60. For the final FY 2023 Federal per diem base rate, we applied the payment rate update of 3.8 percent—that is, the 2016-based IPF market basket increase for FY 2023 of 4.1 percent less the productivity adjustment of 0.3 percentage point—and the wage index budget-neutrality factor of 1.0012 (as discussed in section IV.D.1 of this final rule) to the FY 2022 Federal per diem base rate of $832.94, yielding a final Federal per diem base rate of $865.63 for FY 2023. Similarly, we applied the 3.8 percent payment rate update and the 1.0012 wage index budget-neutrality factor to the FY 2022 ECT payment per treatment of $358.60, yielding a final ECT payment per treatment of $372.67 for FY 2023.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such RY, the Secretary will reduce any annual update to a standard Federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage points reduction to the Federal per diem base rate and the ECT payment per treatment as follows:

- For IPFs that fail to report required data under the IPFQR Program, we applied a 1.8 percent payment rate update—that is, the IPF market basket increase for FY 2023 of 4.1 percent less the productivity adjustment of 0.3 percentage point for an update of 3.8 percent, and further reduced by 2.0 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act—and the wage index budget-neutrality factor of 1.0012 to the FY 2022 Federal per diem base rate of $832.94, yielding a Federal per diem base rate of $848.95 for FY 2023.
- For IPFs that fail to report required data under the IPFQR Program, we applied the 1.8 percent annual payment rate update and the final 1.0012 wage index budget-neutrality factor to the FY 2022 ECT payment per treatment of $358.60, yielding an ECT payment per treatment of $365.49 for FY 2023.

C. Updates to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). We proposed to continue to use the existing regression-derived adjustment factors established in 2005 for FY 2023. However, we have used more recent claims data to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates.

2. IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS–DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

a. Update to MS–DRG Assignment

We believe it is important to maintain for IPFs the same diagnostic coding and Diagnosis Related Group (DRG) classification used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005,

we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (MS–DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS' effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS–DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and the November 15, 2004 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2023, we did not propose any changes to the IPF MS–DRG adjustment factors. Therefore, we are retaining the existing IPF MS–DRG adjustment factors.

In the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)'' (79 FR 45945 through 45947), we finalized conversions of the ICD–9–CM-based MS–DRGs to ICD–10–CM/PCS-based MS–DRGs, which were implemented on October 1, 2015. Further information on the ICD–10–CM/PCS MS–DRG conversion project can be found on the CMS ICD–10–CM website at *https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.*

For FY 2023, we proposed to continue making the existing payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS–DRGs listed in Addendum A. Addendum A is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.* Psychiatric principal diagnoses that do not group to one of the 17 designated MS–DRGs will still receive the Federal per diem base rate and all other applicable adjustments; however, the payment will not include an MS–DRG adjustment. The diagnoses for each IPF MS–DRG will be updated as of October 1, 2022, using the final IPPS FY 2023 ICD–10–CM/PCS code sets. The FY 2023 IPPS/LTCH PPS final rule includes tables of the changes to the ICD–10–CM/PCS code sets, which underlie the FY 2023 IPF MS–DRGs. Both the FY 2023 IPPS final rule and the tables of final changes to the ICD–10–CM/PCS code sets, which underlie the FY 2023 MS–DRGs, are available on the CMS IPPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Code First

As discussed in the ICD–10–CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, ICD–10–CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a ''use additional code'' note at the etiology code, and a ''code first'' note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD–10–CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a ''code first'' note, the provider will follow the instructions in the ICD–10–CM Tabular List. The submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

For more information on the code first policy, we refer readers to the November 2004 IPF PPS final rule (69 FR 66945) and see sections I.A.13 and I.B.7 of the FY 2020 ICD–10–CM Coding Guidelines, available at *https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf.* In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD–10–CM that were present in ICD–9–CM (79 FR 46009). In FY 2022 there were 18 codes finalized for deletion from the ICD–10–CM codes in the IPF Code First table. For FY 2023, we proposed to delete 2 ICD–10–PCS codes and add 48 ICD–10–PCS codes to the IPF Code First table. For this FY 2023 IPF PPS final rule, we are finalizing our proposal to delete 2 ICD–10–PCS codes to add 48 ICD–10–PCS codes to the IPF Code First table. The FY 2023 Code First table is shown in Addendum B on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

b. Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat. In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD–9–CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD–10–CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD–9–CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system,

which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign an MS–DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD–9–CM codes were converted to ICD–10–CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD–10–CM implementation as it will be if the same record had been coded in ICD–9–CM and submitted prior to ICD–10–CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2023, we proposed to continue to use the same comorbidity adjustment factors in effect in FY 2022. The FY 2023 comorbidity adjustment factors are found in Addendum A, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

For FY 2023, we proposed to add 10 ICD–10–CM/PCS codes and remove 1 ICD–10–CM/PCS code from the Coagulation Factor category; proposed to add 3 ICD–10–CM/PCS codes and remove 11 ICD–10–CM/PCS codes from the Oncology Treatment comorbidity category; and proposed to add 4 ICD–10–CM/PCS codes to the Poisoning comorbidity category.

Comment: One commenter expressed concerns that the proposed FY 2023 comorbidity codes detailed in Addenda B were not displayed on the CMS website at the time the proposed rule was posted.

Response: We appreciate the concern that this commenter raised. Due to unanticipated technical issues, we were unable to post the B addenda until a few days after the display of the proposed rule. We apologize for any inconvenience that this delay caused, and will continue to work to ensure that addenda are posted as soon as possible after the display of the proposed rule for each FY. We encourage readers to contact the IPF Payment Policy mailbox at *IPFPaymentPolicy@cms.hhs.gov* in order to bring issues like this to our attention as soon as possible.

The proposed FY 2023 comorbidity codes are shown in Addenda B, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2023 ICD–10–CM codes to remove codes that were site ''unspecified'' in terms of laterality from the FY 2023 ICD–10–CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients' diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site ''unspecified'' codes from the IPF PPS ICD–10–CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. There were no proposed changes to the FY 2023 ICD–10–CM/PCS codes, therefore, we did not propose to remove any of the new codes.

c. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are costlier than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. For FY 2023, we proposed continuing to use the patient age adjustments currently in effect in FY 2022, as shown in Addendum A of this rule (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*). We did not receive any comments on this proposal and are finalizing it as proposed.

d. Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the length of stay (LOS) increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the November 2004 IPF PPS final rule, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 through 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section IV.D.4 of this final rule.

For FY 2023, we proposed to continue to use the variable per diem adjustment factors currently in effect, as shown in Addendum A to this rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.* A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

D. Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), RY 2009 IPF PPS (73 FR 25719) and the RY 2010 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

Due to the variation in costs and because of the differences in geographic wage levels, in the November 2004 IPF PPS final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-

specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals so the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF specific wage index. As discussed in the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without considering geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy at § 412.424(a)(2) provides that we use the best Medicare data available to estimate costs per day, including an appropriate wage index to adjust for wage differences.

When the IPF PPS was implemented in the November 2004 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to the FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020, we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized the use of the pre-floor, pre-reclassified IPPS hospital wage index from the FY concurrent with the IPF FY as the basis for the IPF wage index. For example, the FY 2020 IPF wage index was based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the FY 2020 proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified IPPS hospital wage index will result in the most up-to-date wage data being the basis for the IPF wage index. We noted that it would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. We indicated that the Medicare skilled nursing facility (SNF) PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. CMS proposed and finalized similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. Thus, the wage adjusted Medicare payments of various provider types are based upon wage index data from the same timeframe. For FY 2023, we proposed to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

Comment: One commenter recommended we revise our policy so that the post-reclassification and post-floor hospital inpatient PPS wage index is used to calculate the wage index for IPFs. The commenter believe that the continued use of the pre-reclassification and pre-floor hospital inpatient wage index is unreasonable because it places IPFs at a disadvantage in the labor markets in which they operate relative to hospitals in the same markets. Another commenter recommended the application of a non-budget neutral wage index floor along with an annual cap on CBSAs with high wage indices and asserted that that the impact of certain wage index changes could be eliminated by allowing IPFs to reclassify to another CBSA as they are permitted to do under the IPPS.

Response: We appreciate the commenters' recommendations. We did not propose the specific policies suggested by commenters, but we will take them into consideration to potentially inform future rulemaking. We do not believe that the continued use of the pre-reclassification and pre-floor hospital inpatient wage index for FY 2023 is unreasonable or that this policy puts IPFs at a disadvantage relative to hospitals in the labor markets in which they operate. As we have previously discussed in the RY 2007 final rule (71 FR 27066), we believe that the actual location of an IPF (as opposed to the location of affiliated providers) is most appropriate for determining the wage adjustment because the prevailing wages in the area in which the IPF is located influence the cost of a case. In that same RY 2007 final rule (71 FR 27066), we also stated that we believe the ''rural floor'' is required only for the acute care hospital payment system, because section 4410 of the Balanced Budget Act of 1997 (Pub. L. 105–33) applies specifically to acute care hospitals and not excluded hospitals and excluded units. Therefore, we believe using the pre-floor, pre-reclassified IPPS hospital wage index is the best available data to use as a proxy for an IPF wage index because it best reflects the variation in local labor costs of IPFs in the various geographic areas in which they are located and uses the most recent IPPS hospital wage data without any geographic reclassifications, floors, or other adjustments.

Final Decision: After consideration of the comments received, we are finalizing our proposal for FY 2023 to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

We will apply the IPF wage index adjustment to the labor-related share of the national base rate and ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment will change from 77.2 percent in FY 2022 to 77.4 percent in FY 2023. This percentage reflects the labor-related share of the 2016-based IPF market basket for FY 2023 (see section IV.A of this rule).

b. Office of Management and Budget (OMB) Bulletins

1. Background

The wage index used for the IPF PPS is calculated using the unadjusted, pre-reclassified and pre-floor IPPS wage index data and is assigned to the IPF on the basis of the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. These bulletins contain information regarding CBSA changes, including changes to CBSA numbers and titles. OMB bulletins may be accessed online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*. In accordance with our established methodology, the IPF PPS has historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index and, when necessary and appropriate, has proposed and finalized transition policies for these changes.

In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs, and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721).

Subsequently, CMS adopted the changes that were published in past OMB bulletins in the FY 2016 IPF PPS final rule (80 FR 46682 through 46689), the FY 2018 IPF PPS rate update (82 FR 36778 through 36779), the FY 2020 IPF PPS final rule (84 FR 38453 through 38454), and the FY 2021 IPF PPS final rule (85 FR 47051 through 47059). We direct readers to each of these rules for more information about the changes that were adopted and any associated transition policies.

In part due to the scope of changes involved in adopting the CBSA delineations for FY 2021, we finalized a 2-year transition policy in the FY 2021 IPF PPS final rule consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of certain wage index policy changes. We applied a 5-percent cap on wage index decreases to all IPF providers that had any decrease in their wage indexes, regardless of the circumstance causing the decline, so that an IPF's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020, regardless of whether the IPF was part of an updated CBSA. We refer readers to the FY 2021 IPF PPS final rule (85 FR 47058 through 47059) for a more detailed discussion about the wage index transition policy for FY 2021.

On March 6, 2020, OMB issued OMB Bulletin 20–01 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In considering whether to adopt this bulletin, we analyzed whether the changes in this bulletin would have a material impact on the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area. As discussed in further detail in section IV.D.1.b.ii of this final rule since Micropolitan areas are considered rural for the IPF PPS wage index, this bulletin has no material impact on the IPF PPS wage index. That is, the constituent county of the new Micropolitan area was considered rural effective as of FY 2021 and would continue to be considered rural if we adopted OMB Bulletin 20–01. Therefore, we did not propose to adopt OMB Bulletin 20–01 in the FY 2022 IPF PPS proposed rule.

2. Micropolitan Statistical Areas

OMB defines a ''Micropolitan Statistical Area'' as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's IPF PPS rural wage index. We refer readers to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural.

c. Permanent Cap on Wage Index Decreases

As discussed in section IV.D.1.b.(1) of this final rule, we have proposed and finalized temporary transition policies in the past to mitigate significant changes to payments due to changes to the IPF PPS wage index. Specifically, for FY 2016 (80 FR 46652), we implemented a 50/50 blend for all geographic areas consisting of the wage index values computed using the then-current OMB area delineations and the wage index values computed using new area delineations based on OMB Bulletin No. 13–01. In FY 2021 (85 FR 47059), we implemented a 2-year transition to mitigate any negative effects of wage index changes by applying a 5-percent cap on any decrease in an IPF's wage index from the IPF's final wage index from FY 2020. We explained that we believe the 5-percent cap would provide greater transparency and would be administratively less complex than the prior methodology of applying a 50/50 blended wage index. We indicated that no cap would be applied to the reduction in the wage index for the second year, that is, FY 2022, and that this transition approach struck an appropriate balance by providing a transition period to mitigate the resulting short-term instability and negative impacts on providers and time for them to adjust to their new labor market area delineations and wage index values.

In FY 2022 (86 FR 42616 through 42617), a couple of commenters recommended CMS extend the transition period adopted in the FY 2021 IPF PPS final rule. We did not propose to modify the transition policy that was finalized in the FY 2021 IPF PPS final rule, and we did not extend the transition period for FY 2022. In the FY 2022 IPF PPS final rule, we stated that we continued to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions associated with the adoption of the revised CBSA delineations in FY 2021, allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in IPF payments and improving the accuracy of the payment adjustment for differences in area wage levels. However, we acknowledged that certain changes to wage index policy may significantly affect Medicare payments.

In addition, we reiterated that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking. With these policy principles in mind, we considered for the FY 2023 proposed rule how best to address the potential scenarios about which commenters raised concerns; that is, scenarios in which changes to wage index policy may significantly affect Medicare payments.

In the past, we have established transition policies of limited duration to phase in significant changes to labor market areas. In taking this approach in the past, we sought to mitigate short-term instability and fluctuations that can negatively impact providers due to wage index changes. In accordance with the requirements of the IPF PPS wage index regulations at § 412.424(a)(2), we use an appropriate wage index based on the best available data, including the best available labor market area delineations, to adjust IPF PPS payments for wage differences. We have previously stated that, because the wage index is a relative measure of the value of labor in prescribed labor market areas, we believe it is important to implement new labor market area delineations with as minimal a transition as is reasonably possible. However, we recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain providers even when labor market areas do not change. In addition, year-to-year fluctuations in an area's wage index can occur due to external factors beyond a provider's control, such as the COVID–19 PHE, and for an individual provider, these fluctuations can be difficult to predict. We also recognize that predictability in Medicare payments is important to enable providers to budget and plan their operations.

In light of these considerations, we proposed a permanent approach to smooth year-to-year changes in providers' wage indexes. We proposed a policy that we believe increases the predictability of IPF PPS payments for providers and mitigates instability and significant negative impacts to providers resulting from changes to the wage index. As previously discussed, we believe applying a 5-percent cap on wage index decreases for FY 2021 provided greater transparency and was administratively less complex than prior transition methodologies. In addition, we believe this methodology mitigated short-term instability and fluctuations that can negatively impact providers due to wage index changes. Lastly, we believe the 5-percent cap applied to all wage index decreases for FY 2021 provided an adequate safeguard against significant payment reductions related to the adoption of the revised CBSAs. However, as discussed earlier in this section of the proposed rule, we recognize there are circumstances that a 2-year mitigation policy, like the one adopted for FY 2021, would not effectively address future years in which providers continue to be negatively affected by significant wage index decreases.

We explained in the FY 2023 IPF PPS proposed rule (87 FR 19424) that typical year-to-year variation in the IPF PPS wage index has historically been within 5 percent, and we expected this will continue to be the case in future years. Because providers are usually experienced with this level of wage index fluctuation, we stated that we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in IPF PPS payments due to any significant wage index decreases that may affect providers in a year. Therefore, we believe this approach would address concerns about instability that commenters raised in the FY 2022 IPF PPS rule. In addition, we noted that we believe applying a 5-percent cap on all wage index decreases would support increased predictability about IPF PPS payments for providers, enabling them to more effectively budget and plan their operations. Lastly, because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system, we believe it would ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. As discussed in further detail in section IV.D.1.e of this final rule, we estimated that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for FY 2023. Because the wage index is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average, we explained that we anticipated that in the absence of proposed policy changes most providers would not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we anticipated that the impact to the wage index budget neutrality factor in future years would continue to be minimal. We also stated that we believe that the 5-percent cap would likely be applied similarly to all IPFs in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) will be similar. We explained that, while this policy may result in IPFs in a CBSA receiving a higher wage index than others in the same area (such as situations when delineations change), we believe the impact would be temporary.

The Secretary has broad authority under section 1886(s)(1) of the Act and Section 124 of the BBRA to establish appropriate payment adjustments under the IPF PPS, including the wage index adjustment. As discussed earlier in this section, the IPF PPS regulations specify that we use an appropriate wage index based on the best available data. For the reasons discussed in this section, we stated in the proposed rule that we believe a 5-percent cap on wage index decreases would be appropriate for the IPF PPS (87 FR 19424). Therefore, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we proposed that an IPF's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, regardless of whether the IPF is part of an updated CBSA, and that for subsequent years, a provider's wage index would not be less than 95 percent of its wage index calculated in the prior FY. This also means that if an IPF's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the IPF's capped wage index in the prior FY. For example, if an IPF's wage index for FY 2023 is calculated with the application of the 5-percent cap, then its wage index for FY 2024 would not be less than 95 percent of its capped wage index in FY 2023. Lastly, we proposed that a new IPF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IPF would not have a wage index in the prior FY. We proposed to reflect the permanent cap on wage index decreases at § 412.424(d)(1)(i).

Comment: We received 11 comments supporting the proposal of a permanent cap on wage index decreases. One commenter recommended that CMS consider a more gradual reduction of the

wage index cap, such as between 1 and 2 percent.

Response: We appreciate commenters' support for the proposed permanent cap on wage index decreases. We also appreciate the suggestion to consider a lower threshold for the permanent cap; however, we are not finalizing a lower threshold for the cap. Furthermore, as we discussed in the FY 2023 IPF PPS proposed rule (87 FR 19424), we believe applying a 5-percent cap on wage index decreases would be appropriate for the IPF PPS, because it would effectively mitigate instability in IPF PPS payments due to any significant wage index decreases, and would also represent a small overall impact on the labor market area wage index system and would therefore ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. Based on the data used for this FY 2023 IPF PPS final rule, we estimate that only 1.3 percent of providers will experience wage index changes of more than 5 percent. In contrast, we estimate that approximately 12.2 percent of providers will experience wage index decreases of more than 2 percent, and 32.1 percent will experience wage index decreases of more than 1 percent. Therefore, if we were to cap wage index decreases at a lower threshold, for example 1 or 2 percent as the commenter suggested, the wage index cap would affect more providers and, accordingly, would result in a larger budget neutrality effect. Furthermore, the wage index cap policy would represent a relatively larger overall impact on the labor market area wage index system, since more IPFs in a greater number of labor market areas would be affected by the cap. We therefore do not believe it would be appropriate to apply a 1 or 2 percent cap on wage index decreases as the commenter suggested.

Comment: MedPAC supported the proposal to cap wage index decreases at 5 percent, but suggested also applying a cap to increases of more than 5 percent.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the proposed rule, one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. As we noted in the FY 2023 IPF PPS proposed rule (87 FR 19424), we believe applying a 5-percent cap on all wage index decreases would support increased predictability about IPF PPS payments for providers, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of IPF PPS payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable IPFs to more effectively budget and plan their operations. Therefore, we believe it is appropriate for providers that experience an increase in their wage index value to receive that wage index value.

Comment: Several commenters recommended that CMS apply the wage index cap in a non-budget neutral manner.

Response: In accordance with our longstanding policy under the IPF PPS, we updated the wage index in such a way that total estimated payments to IPFs for FY 2023 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We proposed to apply the wage index cap in a budget-neutral manner in accordance with this overall budget neutrality policy for the IPF PPS wage index so that wage index changes do not increase aggregate Medicare spending. In the FY 2023 IPF PPS proposed rule, we noted that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for FY 2023. We explained that we anticipate that in the absence of proposed policy changes most providers will not experience year-to-year wage index declines greater than 5 percent in any given year and that we expect the impact to the wage index budget neutrality factor in future years will continue to be minimal.

Comment: Two commenters opposed the proposal to pay any new provider the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied. One commenter expressed concern that this policy will create an unnecessary inequity in Medicare payments for IPFs in the same market. Another commenter asserted that new facilities will struggle to fill hospital beds and recruit staff if their wage index is lower than other IPFs in the same CBSA. This commenter further noted that ultimately, the addition of a new facility will most likely increase the region's wage index in the future.

Response: We appreciate the concerns that commenters raised, but we do not agree that this proposal would create an unnecessary inequity in IPF PPS payments or make it more difficult for new facilities to fill hospital beds and recruit staff. As we discussed in the FY 2023 IPF PPS proposed rule (87 FR 19424), while this policy may result in IPFs in a CBSA receiving a higher wage index than others in the same area (such as situations when delineations change), we believe the impact would be temporary because, over time, wage levels in a CBSA will converge to the same level. In addition, as we have previously stated, we believe the IPF PPS wage index accurately reflects the cost of labor in a prescribed labor market area. Therefore, we believe the IPF PPS wage index would accurately reflect the labor costs that a new provider would face. As we noted earlier in this section, we proposed to apply the permanent 5-percent cap on wage index decreases in order to mitigate instability, support increased predictability about IPF PPS payments, and enable providers to more effectively budget and plan their operations. We do not believe that changes to the wage index in a labor market area would represent a change for a new provider in that labor market area. In contrast to other providers in the same area, a new provider would not have a prior year wage index against which to compare the current year wage index. Therefore, we do not believe that applying the cap to new providers would be appropriate.

Comment: A commenter recommended that CMS retroactively apply the 5-percent cap policy to the FY 2022 wage index for providers that experienced wage index decreases due to their transition to a new CBSA based on the new OMB delineations that were finalized for FY 2021.

Response: As noted previously, in FY 2021, we implemented a 2-year transition to mitigate any negative effects of wage index changes by applying a 5-percent cap on any decrease in an IPF's wage index from the IPF's final wage index from FY 2020; we indicated that no cap would be applied to the reduction in the second year, FY 2022. In the FY 2023 IPF PPS proposed rule, we did not propose to modify that transition policy to extend the transition period for FY 2022. We have historically implemented transitions of limited duration, as discussed in the FY 2016 (80 FR 46652) final rule, to address CBSA changes due to substantial updates to OMB delineations. In accordance with our policy principles that we use the most updated data and information available with regard to the wage index, as noted in the FY 2022 IPF PPS final rule (86 FR 42617), we proposed that the FY 2023 IPF PPS 5-percent cap wage index policy would be prospective to mitigate any significant decreases beginning in FY 2023.

Final Decision: After consideration of the comments received, we are finalizing as proposed a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, which we will apply in a budget-neutral manner. We are also finalizing as proposed that a new IPF will be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IPF would not have a wage index in the prior FY. We are reflecting the permanent cap on wage index decreases at § 412.424(d)(1)(i).

As previously discussed, we believe this methodology will maintain the IPF PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of IPF PPS payments for providers, and mitigate instability and significant negative impacts to providers resulting from significant changes to the wage index. In section VIII.C.2 of this final rule, we estimate the impact to payments for providers in FY 2023 based on this policy. We also note that we will examine the effects of this policy on an ongoing basis in the future in order to assess its appropriateness.

d. Adjustment for Rural Location

In the November 2004 IPF PPS final rule, (69 FR 66954) we provided a 17-percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17-percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17-percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. For FY 2023, we proposed to continue to apply a 17-percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C) (see 69 FR 66954 for a complete discussion of the adjustment for rural locations). We did not receive any comments on this proposal, and we are finalizing it as proposed.

e. Budget Neutrality Adjustment

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. For FY 2023, we proposed to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2023 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. As discussed in section IV.E.2 of this final rule, we used the March 2022 update of the FY 2021 IPF claims to calculate the final FY 2023 IPF PPS wage index budget neutrality factor. We used the following steps, which include the 5-percent cap on decreases to a provider's wage index, to ensure that the rates reflect the FY 2023 update to the wage indexes (based on the FY 2019 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2022 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2022 IPF PPS final rule (86 FR 42608).

Step 2: Simulate estimated IPF PPS payments using the final FY 2023 IPF wage index values (available on the CMS website), including application of the 5-percent cap on wage index decreases, and the final FY 2023 labor-related share (based on the latest available data as discussed previously).

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2023 budget-neutral wage adjustment factor of 1.0012.

Step 4: Apply the FY 2023 budget-neutral wage adjustment factor from step 3 to the FY 2022 IPF PPS Federal per diem base rate after the application of the market basket update described in section IV.A of this final rule, to determine the FY 2023 IPF PPS Federal per diem base rate.

As discussed in section IV.D.1.c of this final rule, we also followed these steps to separately calculate the budget neutrality factor associated with the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. First, we calculated the budget neutrality factor associated with the FY 2023 IPF wage index and FY 2023 labor-related share. We divided the amount of simulated payments using the FY 2022 IPF wage index and labor-related share by the amount of simulated payments using the FY 2023 wage index and FY 2023 labor-related share. The resulting quotient is 1.0013.

Next, we calculated the budget neutrality factor associated with the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. We divided the amount of simulated payments using the FY 2023 wage index and FY 2023 labor-related share by the amount of simulated payments using the FY 2023 wage index, the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and the FY 2023 labor-related share. The resulting quotient is 0.9999. The combined budget neutrality factor, which is the FY 2023 budget-neutral wage adjustment factor as discussed earlier in this section, is 1.0012.

2. Teaching Adjustment

In the November 2004 IPF PPS final rule (69 FR 66922), we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census (ADC).

Under the IPPS, Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. In addition, direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's ''teaching variable,'' which is (1 + (the number of FTE residents training in the IPF/the IPF's ADC)). The teaching variable is then raised to the 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described in this section of the final rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of

residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a ''base year'' and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (publication date of the IPF PPS final rule). A complete discussion of the temporary adjustment to the FTE cap to reflect residents due to hospital closure or residency program closure appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456).

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data. Therefore, in this FY 2023 final rule, we will continue to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

3. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare prospective payment systems (for example, the IPPS and LTCH PPS) adopted a COLA to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii will improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the non-labor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors through 2009 were published by the Office of Personnel Management (OPM), and the OPM memo showing the 2009 COLA factors is available at *https://www.chcoc.gov/content/nonforeign-area-retirement-equity-assurance-act.*

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- Rest of the state of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Non-foreign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for FY 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of NDAA, locality pay was phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the RY 2012 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates, which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment. Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014.

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), we established a new methodology to update the COLA factors for Alaska and Hawaii, and adopted this methodology for the IPF PPS in the FY 2015 IPF final rule (79 FR 45958 through 45960). We adopted this new COLA methodology for the IPF PPS because IPFs are hospitals with a similar mix of commodities and services. We believe it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, the IPF COLAs for FY 2015 through FY 2017 were the same as those applied under the IPPS in those years. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), the COLA updates are determined every 4 years, when the IPPS market basket labor-related share is updated. Because the labor-related share of the IPPS market basket was most recently updated for FY 2022, the COLA factors were updated in FY 2022 IPPS/LTCH rulemaking (86 FR 45547). As such, we also updated the IPF PPS COLA factors for FY 2022 (86 FR 42621 through 42622) to reflect the updated COLA factors finalized in the FY 2022 IPPS/LTCH rulemaking. Table 2 shows the IPF PPS COLA factors effective for FY 2022 through FY 2025.

TABLE 2: IPF PPS Cost-of-Living Adjustment Factors: IPFs Located in Alaska and Hawaii

Area	FY 2022 through FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

We did not receive any comments about the proposed COLA factors for FY 2023, and are finalizing them as proposed. The IPF PPS COLA factors for FY 2023 are also shown in Addendum A to this final rule, and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

4. Adjustment for IPFs With a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED or an excluded psychiatric unit of an IPPS hospital or a CAH, for preadmission services otherwise payable under the Medicare Hospital Outpatient Prospective Payment System (OPPS), furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)), and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception which we described), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. Those IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described in this section of the final rule. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an IPPS hospital or CAH and admitted to the same hospital's or CAH's excluded psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF. For FY 2023, we proposed to continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. We did not receive any comments on this proposal, and we are finalizing it as proposed. A complete discussion of the steps involved in the calculation of the ED adjustment factors are in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).

E. Other Final Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require costlier care, and therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF

payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2-percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we proposed to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2-percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

Our longstanding methodology for updating the outlier fixed dollar loss threshold involves using the best available data, which is typically the most recent available data. Last year for the FY 2022 IPF PPS final rule, we finalized the use of FY 2019 claims rather than the more recent FY 2020 claims for updating the outlier fixed dollar loss threshold (86 FR 42623). We noted that our use of the FY 2019 claims to set the final outlier fixed dollar loss threshold for FY 2022 deviated from our longstanding practice of using the most recent available year of claims, but remained otherwise consistent with the established outlier update methodology. We explained that we finalized our proposal to deviate from our longstanding practice of using the most recent available year of claims only because, and to the extent that, the COVID–19 PHE appeared to have significantly impacted the FY 2020 IPF claims. We further stated that we intended to continue to analyze further data in order to better understand both the short-term and long-term effects of the COVID–19 PHE on IPFs (86 FR 42624).

For the FY 2023 IPF PPS proposed rule, consistent with our longstanding practice, we analyzed the most recent available data for simulating IPF PPS payments in FY 2023. We observed a continuation of two main trends that we noted in our analysis of FY 2020 claims for FY 2022—that is, an overall increase in average cost per day and an overall decrease in the number of covered days. However, we also identified that some providers had significant increases in their charges, resulting in higher than normal estimated cost per day that would skew our estimate of outlier payments for FY 2022 and FY 2023.

In the proposed rule (87 FR 19428), we noted that historically, we have applied statistical trims under the IPF PPS in order to improve the statistical validity of the data used for ratesetting. In the November 2004 final rule, we explained that we applied a 3 standard deviation trim on cost per day prior to calculating the average per diem cost used to calculate the IPF PPS Federal per diem base rate (69 FR 66927). Furthermore, as discussed in section IV.E.3 of this final rule, our longstanding policy applies a ceiling on a provider's cost-to-charge ratio when it exceeds 3 standard deviations from the mean cost-to-charge ratio for urban or rural providers. We proposed a similar approach in order to address the skew in estimated cost per day that we observed in the FY 2021 claims. Specifically, we proposed for FY 2023 to exclude providers from our simulation of IPF PPS payments for FY 2022 and FY 2023 if their change in estimated average cost per day is outside 3 standard deviations from the mean.

In the proposed rule (87 FR 19428), we stated that based on an analysis of the December 2021 update of FY 2021 IPF claims and the FY 2022 rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. We proposed to update the IPF outlier threshold amount for FY 2023 using FY 2021 claims data and the same methodology that we used to set the initial outlier threshold amount in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier threshold amounts for years 2008 through 2022. However, as discussed earlier in this section, we also proposed for FY 2023 to exclude providers from our impact simulations whose change in simulated cost per day is outside 3 standard deviations from the mean. Based on an analysis of the data available for the proposed rule, we estimated that IPF outlier payments as a percentage of total estimated payments were approximately 3.2 percent in FY 2022. Therefore, we proposed to update the outlier threshold amount to $24,270 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2023. This proposed update was an increase from the FY 2022 threshold of $16,040.

Comment: Several commenters expressed concern about using CY 2021 data because of the impact of the COVID–19 PHE and suggested that CMS consider alternative methodologies for estimating the outlier percentage and setting the outlier fixed dollar loss threshold amount. Some commenters expressed their belief that the proposed trimming methodology is not sufficient to blunt COVID–19's overstated impact on the IPF PPS outlier calculation. These commenters encouraged CMS to use an alternative inflation factor from a period before the COVID–19 PHE and to adjust cost-to-charge ratios (CCRs) to reflect the CCRs from prior to the COVID–19 PHE. Another commenter suggested that CMS estimate the outlier percentage using multiple years of claims, or set the outlier fixed dollar loss threshold amount based on an average of outlier thresholds from multiple years. Another commenter suggested that the percent increase to the outlier fixed dollar loss threshold amount should be limited to no more than the market basket update percentage.

Response: We appreciate the suggestions from commenters regarding these alternative methodologies. We believe that the proposed trimming methodology sufficiently mitigates the significant increases in charges that we observed in the FY 2021 claims, which we noted would skew our estimate of outlier payments for FY 2022. We believe this methodology also appropriately accounts for the ongoing trends that we noted in previous analysis of FY 2020 claims for FY 2022—that is, an overall increase in average cost per day and an overall decrease in the number of covered days. In the FY 2022 IPF PPS final rule (86 FR 42624), we explained that we believed these trends were related to the COVID–19 PHE and noted that we would continue to analyze further data in order to better understand both the short-term and long-term effects of the COVID–19 PHE on IPFs. Because we observed these continued trends in FY 2021, we believe it is reasonable to expect that they will continue to some extent in FY 2023.

Regarding the recommendation to use an inflation factor from a different time

period, we do not believe it would be appropriate to do so for this FY 2023 IPF PPS final rule. We note that whereas the IPPS uses a charge inflation factor calculated based on historical IPPS charge data, the longstanding IPF PPS methodology uses a charge inflation factor calculated based on the latest available forecast of the IPF PPS market basket price proxies. As discussed in section IV.A.2 of this final rule, we believe the 2016-based IPF market basket increase adequately reflects the average change in the price of goods and services hospitals purchase in order to provide IPF medical services. Furthermore, as discussed in that same section of this final rule, the updated forecast for this FY 2023 final rule incorporates more recent historical data and reflects a revised outlook regarding the United States economy and expected price inflation for FY 2023 for IPFs. Therefore, we believe it is more appropriate to use an inflation factor that is based on the latest available forecast of input price growth for IPFs, rather than a factor based on data from an earlier time period, as the commenters suggested.

Regarding the alternative methodologies that commenters suggested for calculating the outlier threshold, we do not believe that averaging the proposed FY 2023 outlier fixed dollar loss threshold amount with the amounts from prior years, or limiting the increase to the outlier fixed dollar loss threshold amount, would be appropriate for this FY 2023 IPF PPS final rule. As discussed earlier in this section, the longstanding IPF PPS 2-percent outlier policy was established based on the regression analysis and payment simulations used to develop the IPF PPS. We have previously explained that the 2-percent outlier policy strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments. For this FY 2023 IPF PPS final rule, we have simulated payments using the latest available data, and these payment simulations indicate that an increase to the outlier fixed dollar loss threshold is necessary in order to maintain outlier payments at 2 percent of total payments. We are concerned that the alternative methodologies that commenters suggested would not appropriately target outlier payments such that they remain at 2 percent of total IPF PPS payments. Regarding the suggestion that CMS use multiple years of claims to determine the outlier fixed dollar loss threshold amount, we reiterate that our longstanding methodology uses the best available data, which is typically the most recent available data, to update the outlier fixed dollar loss threshold amount. We believe the proposed methodology appropriately accounts for the trends in average cost per day and the number of covered days reflected in the IPF PPS claims, which we expect are likely to continue to some extent into FY 2023. We believe the proposed methodology also incorporates more recent historical data and reflects a revised outlook regarding the United States economy and expected price inflation for FY 2023 for IPFs. Therefore, we are finalizing the use of the proposed methodology to calculate the FY 2023 IPF PPS outlier fixed dollar loss threshold amount.

Comment: MedPAC encouraged CMS to provide additional data about the increase to the outlier fixed dollar loss threshold amount for FY 2023.

Response: As we noted in the proposed rule, two main trends that we observed in the FY 2020 claims continued in the FY 2021 claims. First, we observed that average cost per day increased approximately 12 percent when comparing the simulated FY 2021 IPF PPS payments from the FY 2022 IPF PPS final rule to the simulated FY 2022 IPF PPS payments that we used to estimate the outlier percentage for this FY 2023 IPF PPS final rule. In the FY 2022 IPF PPS proposed rule (86 FR 19526), we explained that we estimate the costs per case based on the covered charges on each IPF claim and the IPF's most recent CCR. In that proposed rule, we noted that laboratory charges, which make up roughly one-third of the covered charges per IPF claim, increased approximately 6.8 percent between FY 2019 and FY 2020. We found that laboratory charges continued to increase for the FY 2021 claims analyzed for this FY 2023 IPF PPS final rule. We found that laboratory charges per day in 2021 were approximately 12.7 percent higher than laboratory charges per day in 2019. We believe these increased laboratory charges are likely in response to the COVID–19 PHE, and as stated earlier, we believe it is reasonable to expect that these increased laboratory charges will continue to some extent in FY 2023.

The second continued trend that we observed was that the number of covered days decreased in the FY 2021 claims. As we discussed in the FY 2022 IPF PPS proposed rule (86 FR 19524), we observed a decrease in covered days of approximately 15 percent from the FY 2019 claims to the FY 2020 claims. Before applying the statistical trim for this FY 2023 IPF PPS final rule, the number of covered days in the FY 2021 claims was approximately 28 percent lower than the number of covered days in the FY 2019 claims used for FY 2022 final rulemaking. This decrease in covered days corresponds with a decrease of approximately 27 percent in the total simulated FY 2022 IPF PPS payments compared to total simulated FY 2021 IPF PPS payments used for FY 2022 final rulemaking. After applying the statistical trim, covered days were approximately 32 percent lower than FY 2019, and total simulated FY 2022 IPF PPS payments that we used to estimate the outlier percentage for this FY 2023 IPF PPS final rule were approximately 30 percent lower than total simulated FY 2021 IPF PPS payments. Because we calculate the outlier fixed dollar loss threshold amount so that outlier payments represent 2 percent of total estimated IPF PPS payments, the decrease to the number of days and total estimated IPF PPS payments increases the percentage of outlier payments relative to total payments, which contributes to the upward trend in the outlier fixed dollar loss threshold amount.

In our simulated FY 2022 outlier payments using the FY 2022 IPF PPS outlier fixed dollar loss threshold of $16,040, we estimated that 9,169 cases will receive outlier payments, with a mean outlier payment amount per outlier case of $10,057.59. We observed that the distribution of simulated FY 2022 outlier payments is skewed right, which means that a large number of outlier cases receive relatively small amounts of outlier payments, and a smaller number of outlier cases receive relatively large outlier payments. Consequently, half of all simulated outlier cases receive outlier payments of $5,490.11 or less, and 1,231 cases receive outlier payments of $1,000 or less. We also observed that outlier payments are concentrated among certain types of IPFs. As shown in Table 3, in section VIII.C.2 of this final rule, teaching IPFs with more than 10 percent interns and residents to beds are projected to experience the largest decreases in estimated payments as a result of the increase to the outlier fixed dollar loss threshold amount, because these providers had a larger share of outlier cases than other provider types. We did not observe that changes in case

mix appear to be driving the increase in the outlier percentage. In the simulated FY 2022 IPF PPS payments, we observed that approximately 79 percent of outlier cases are for DRG 885 (Psychoses), which aligns with the proportion of IPF PPS cases that typically receive that DRG. We estimate that the average outlier payment for cases with DRG 885 is $10,600.21, which is comparable to the average outlier payment for all cases.

Final Decision: After consideration of the comments received, we are finalizing our proposal to use the latest available FY 2021 claims, in accordance with our longstanding practice, to simulate payments for determining the final FY 2023 IPF PPS outlier fixed dollar loss threshold amount. We are also finalizing our proposal to exclude providers from our impact simulations whose change in simulated cost per day is outside 3 standard deviations from the mean.

Based on an analysis of the March 2022 update of FY 2021 IPF claims and the FY 2022 rate increases, we continue to believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. We estimate that IPF outlier payments as a percentage of total estimated payments were approximately 3.2 percent in FY 2022. Therefore, we are updating the outlier threshold amount to $24,630 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2023. This update is an increase from the FY 2022 threshold of $16,040.

3. Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall CCR. This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the FY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File (PSF) available.

For FY 2023, we proposed to continue to follow this methodology. We did not receive any comments on this proposal, and we are finalizing it as proposed.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2023 is 2.0412 for rural IPFs, and 1.7437 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the MAC obtains inaccurate or incomplete data with which to calculate a CCR.

We proposed to continue to update the FY 2023 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF. We did not receive any comments on this proposal, and we are finalizing it as proposed. Specifically, for FY 2023, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2022 PSF, we provide an estimated national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4200 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

V. Comment Solicitation on Analysis of IPF PPS Adjustments

In the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we discussed the background of the current IPF PPS patient-level and facility-level adjustment factors, which are the regression-derived adjustment factors from the November 15, 2004 IPF PPS final rule. We briefly discussed past analyses and areas of concern for future refinement, about which we previously solicited comments. Finally, we described the results of the latest analysis of the IPF PPS and solicited comments on certain topics from the report.

As we discussed in the proposed rule, we have undertaken further analysis of more recent IPF cost and claim information. In conjunction with the FY 2023 IPF PPS proposed rule, we posted a report on the CMS website,[2] which summarizes the results of the latest analysis. We noted that this updated analysis finds that the existing IPF PPS model continues to be generally appropriate in terms of effectively aligning IPF PPS payments with the cost of providing IPF services, but suggests that certain updates to the codes, categories, adjustment factors, and ECT payment amount per treatment could improve payment accuracy. We requested comments on the results of our latest analysis as summarized in the report. In particular, we requested comments about the following topics, which are discussed in detail in the report:

- The report summarizes results of the analysis regarding patient-level characteristics, about which we requested comments:

++ The updated regression analysis suggests that certain technical changes to the DRG and comorbidity adjustment factors, consolidation of the age categories for the patient age adjustment, and changes to the adjustment factors for age and length of stay could be appropriate.

++ The analysis of ancillary costs for IPF stays with ECT suggests that a higher ECT payment amount per treatment could better align IPF PPS payments with the costs of furnishing ECT.

++ The analysis of the outlier percentage suggests that fewer IPF cases

[2] The report can be accessed directly via the following link: *https://www.cms.gov/files/document/technical-report-medicare-program-inpatient-psychiatric-facilities-prospective-payment-system.pdf*

qualify for outliers under the current 2 percent outlier target than were estimated when the IPF PPS was established. We estimate that increasing the outlier percentage will increase the number of IPF cases that qualify for outliers, but will have distributional effects due to budget neutrality.

- The report summarizes the results of analysis regarding facility-level characteristics, about which we requested comments:

++ The updated regression analysis suggests that updating the adjustment factors for teaching facilities, rural facilities, and facilities with an ED could improve payment accuracy; however, we estimate such changes could have positive and negative effects on payments for different types of IPFs.

++ The analysis of occupancy-related control variables included in the regression model indicates that these control variables are correlated with the rural adjustment factor, and that removal of these control variables from the model could result in an increase to the rural adjustment factor in the regression model.

- The report summarizes certain areas where we believe additional research is needed. We requested comments about the results summarized in the report. We also requested comments about additional analyses that we should undertake to better understand how these issues affect the cost of providing IPF services, and how the IPF PPS could better account for these costs:

++ We analyzed the costs associated with social determinants of health, but found that our analysis was confounded by a low frequency of IPF claims reporting the applicable ICD–10 diagnosis codes. We solicited public comments on the results of this analysis, and whether there are additional patient characteristics that affect the cost of providing IPF services that may not be consistently reported on claims. Additionally, we solicited public comments about how we could better identify such patient characteristics and their effects on costs.

++ We analyzed the costs associated with the percentage of low-income patients that IPFs treat, based on a construction of the Disproportionate Share Hospitals (DSH) percentage that is used in other payment systems using the data currently available for IPFs. We solicited public comments about the results of this analysis, which suggest that the addition of an adjustment factor for disproportionate share intensity could improve the accuracy of IPF PPS payments.

We received 10 comments in response to the FY 2023 IPF PPS pertaining to the report, the analysis of patient-level and facility-level adjustment factors, and areas of interest for further research. Commenters included MedPAC, state-level and national provider and patient advocacy organizations, and individual IPF hospitals and health systems. We thank commenters for their detailed responses to this comment solicitation. We will take these comments into consideration to potentially inform future rulemaking.

VI. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

A. Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs—Request for Information

Significant and persistent disparities in healthcare outcomes exist in the United States. Belonging to an underserved community is often associated with worse health outcomes.[3] [4] [5] [6] [7] [8] [9] [10] [11] With this in mind, CMS aims to advance health equity, by which we mean the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[12]

We are committed to advancing equity in healthcare outcomes for our beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling them to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[13] Measuring healthcare disparities in quality measures is a cornerstone of our approach to advancing health equity. Hospital performance results that illustrate differences in outcomes between patient populations have been reported to hospitals confidentially since 2018.

The RFI in the proposed rule (87 FR 19429 through 19437) consisted of three sections. The first section discussed a general framework that could be utilized across CMS quality programs to assess disparities in healthcare quality. The next section outlined approaches that could be used in the IPFQR Program to assess drivers of healthcare quality disparities in the IPFQR Program. Additionally, this section discussed measures of health equity that could be adapted for use in the IPFQR Program. Finally, the third section solicited public comment on the principles and approaches listed in the first two sections as well as sought other thoughts about disparity measurement guidelines for the IPFQR Program.

1. Cross-Setting Framework To Assess Healthcare Quality Disparities

CMS has identified five key considerations that we could apply

[3] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[4] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[5] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[6] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[7] Rural Health Research Gateway. (2018). Rural communities: Age, Income, and Health status. Rural Health Research Recap. Available at *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf* . Accessed February 3, 2022.

[8] U.S. Department of Health and Human Services. Office of the Secretary. Progress Report to Congress. HHS Office of Minority Health. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. FY 2020. Available at *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf* . Accessed February 3, 2022.

[9] Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report (MMWR). Heslin, KC, Hall JE. Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. February 5, 2021/70(5); 149–154. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm?s_cid=mm7005a1* _w. Accessed February 3, 2022.

[10] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. medRxiv. 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

[11] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[12] Centers for Medicare and Medicaid Services. Available at *https://www.cms.gov/pillar/health-equity*. Accessed February 9, 2022.

[13] CMS Quality Strategy. 2016. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf*. Accessed February 3, 2022.

consistently across CMS programs when advancing the use of measurement and stratification as tools to address health care disparities and advance health equity. The remainder of this section describes each of these considerations.

a. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measures Stratification Across CMS Quality Programs

By quantifying healthcare disparities through measure stratification (that is, measuring performance differences among subgroups of beneficiaries), we aim to provide useful tools for healthcare providers to drive improvement based on data. We hope that these results support healthcare providers' efforts in examining the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. Quantification of health disparities can also support communities in prioritizing and engaging with healthcare providers to execute such interventions, as well as providing additional tools for accountability and decision-making.

There are several different conceptual approaches to reporting health disparities in the acute care setting, including two complementary approaches that are already used to confidentially provide disparity information to hospitals for a subset of existing measures. The first approach, referred to as the ''within-hospital disparity method,'' compares measure performance results for a single measure between subgroups of patients with and without a given factor. This type of comparison directly estimates disparities in outcomes between subgroups and can be helpful to identify potential disparities in care. This type of approach can be used with most measures that include patient-level data. The second approach, referred to as the ''between-hospital disparity methodology,'' provides performance on measures for only the subgroup of patients with a particular social risk factor. These approaches can be used by a healthcare provider to compare their own measure performance on a particular subgroup of patients against subgroup-specific state and national benchmarks. Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, these approaches may provide detailed information about where differences in care may exist or where additional scrutiny may be appropriate. For example, the between-provider disparity method may indicate that an IPF underperformed (when compared to other facilities on average) for patients with a given social risk factor, which would signal the need to improve care for this population. However, if the IPF also underperformed for patients without that social risk factor, the measured difference, or disparity in care, (the ''within-hospital'' disparity, as described above) could be negligible even though performance for the group that has been historically marginalized remains poor. We refer readers to the technical report describing the CMS Disparity Methods in detail as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the posted Disparity methods Updates and Specifications Report posted on the QualityNet website.[14]

CMS is interested in whether similar approaches to the two discussed in the previous paragraph could be used to produce confidential stratified measure results for selected IPF QRP measures, as appropriate and feasible. However, final decisions regarding disparity reporting will be made at the program-level, as CMS intends to tailor the approach used in each setting to achieve the greatest benefit and avoid unintentional consequences or biases in measurement that may exacerbate disparities in care.

b. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

We intend to expand our efforts to provide stratified reporting for additional clinical quality measures, provided they offer meaningful, actionable, and valid feedback to healthcare providers on their care for populations that may face social disadvantage or other forms of discrimination or bias. We are mindful, however, that it may not be possible to calculate stratified results for all quality measures, and that there may be situations where stratified reporting is not desired. To help inform prioritization of the next generation of candidate measures for stratified reporting, we aim to receive feedback on several systematic principles under consideration that we believe will help us prioritize measures for disparity reporting across programs:

(1) Programs may consider stratification among existing clinical quality measures for further disparity reporting, prioritizing recognized measures which have met industry standards for measure reliability and validity.

(2) Programs may consider measures for prioritization that show evidence that a treatment or outcome being measured is affected by underlying healthcare disparities for a specific social or demographic factor. Literature related to the measure or outcome should be reviewed to identify disparities related to the treatment or outcome, and should carefully consider both social risk factors and patient demographics. In addition, analysis of Medicare-specific data should be done in order to demonstrate evidence of disparity in care for some or most healthcare providers that treat Medicare patients.

(3) Programs may consider establishing statistical reliability and representation standards (for example, the percent of patients with a social risk factor included in reporting facilities) prior to reporting results. They may also consider prioritizing measures that reflect performance on greater numbers of patients to ensure that the reported results of the disparity calculation are reliable and representative.

(4) After completing stratification, programs may consider prioritizing the reporting of measures that show differences in measure performance between subgroups across healthcare providers.

c. Principles for Social Risk Factor and Demographic Data Selection and Use

Social risk factors are the wide array of non-clinical drivers of health known to negatively impact patient outcomes. These include factors such as socioeconomic status, housing availability, and nutrition (among others), often inequitably affecting historically marginalized communities on the basis of race and ethnicity, rurality, sexual orientation and gender identity, religion, and disability.[15] [16] [17] [18] [19] [20] [21] [22]

[14] Centers for Medicare & Medicaid Services (CMS), HHS. Disparity Methods Confidential Reporting. Available at *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.* Accessed February 3, 2022.

[15] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[16] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: retrospective cohort study. British Medical Journal, 346.

[17] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[18] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[19] Rural Health Research Gateway. (2018). Rural communities: Age, Income, and Health status. Rural

Identifying and prioritizing social risk or demographic variables to consider for disparity reporting can be challenging. This is due to the high number of variables that have been identified in the literature as risk factors for poorer health outcomes and the limited availability of many self-reported social risk factors and demographic factors across the healthcare sector. Several proxy data sources, such as area-based indicators of social risk and imputation methods, may be used if individual patient-level data is not available. Each source of data has advantages and disadvantages for disparity reporting:

- Patient-reported data are considered to be the gold standard for evaluating quality of care for patients with social risk factors.[23] While data sources for many social risk factors and demographic variables are still developing among several CMS settings, the IPFQR Program will begin collecting mandatory patient-level data for certain chart-abstracted measures the FY 2024 payment determination and subsequent years (86 FR 42608).
- CMS Administrative Claims data have long been used for quality measurement due to their availability and will continue to be evaluated for usability in measure development and or stratification. Using these existing data allows for high impact analyses with negligible healthcare provider burden. For example, dual eligibility for Medicare and Medicaid has been found to be an effective indicator of social risk in beneficiary populations.[24] There are, however, limitations in these data's usability for stratification analysis.
- Area-based indicators of social risk create approximations of patient risk based on the neighborhood or context that a patient resides in. Several indexes, such as Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[25] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Social Vulnerability Index (SVI),[26] and Health Resources and Services Administration (HRSA) Area Deprivation Index (ADI),[27] provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many social risk factors.
- Imputed data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate patient race and ethnicity. [28]

Health Research Recap. Available at *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.* Accessed February 3, 2022.

[20] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf* Accessed February 3, 2022.

[21] Poteat TC, Reisner SL, Miller M, Wirtz AL. 2020. COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[22] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[23] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1-e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[24] Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk factors and Performance Under Medicare's Value-Based Purchasing Program. December 20, 2016. Available at *https://www.aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.* Accessed February 3, 2022.

[25] Bonito A., Bann C., Eicheldinger C., Carpenter L. *Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries.* Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at *https://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators1.html.* Accessed February 7, 2022.

[26] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. *Journal of Homeland Security and Emergency Management, 8*(1). Available at *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.* Accessed February 3, 2022.

[27] Center for Health Disparities Research. University of Wisconsin School of Medicine and Public health. Neighborhood Atlas. Available at *https://www.neighborhoodatlas.medicine.wisc.edu/* . Accessed February 3, 2022.

[28] Haas A., Elliott M.N., Dembosky J.W., Adams J.L., Wilson-Frederick S.M., Mallett J.S.,, Gaillot S, Haffer S.C., Haviland A.M. (2019). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res,* 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338295/pdf/HESR-54-13.pdf.* Accessed February 3, 2022.

d. Identifying Meaningful Performance Differences

While we aim to use standardized approaches where possible, identifying differences in performance on stratified results will be made at the program level due to contextual variations across programs and settings. We requested comments on the benefits and limitations of the possible reporting approaches described below:

- Statistical approaches could be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm.
- Programs could use a ranked ordering and percentile approach, ordering healthcare providers in a ranked system based on their performance on disparity measures to quickly allow them to compare their performance to other similar healthcare providers.
- Healthcare providers could be categorized into groups based on their performance using defined thresholds, such as fixed intervals of results of disparity measures, indicating different levels of performance.
- Benchmarking, or comparing individual results to state or national average, is another potential reporting strategy.
- Finally, a ranking system may not be appropriate for all programs and care settings, and some programs may only report disparity results.

e. Guiding Principles for Reporting Disparity Measures

Reporting of the results discussed above can be employed in several ways to drive improvements in quality. Confidential reporting, or reporting results privately to healthcare providers, is generally used for new programs or new measures recently adopted for programs through notice and comment rulemaking to give healthcare providers an opportunity to become more familiar with calculation methods and to improve before other forms of reporting are used. In addition, many results are reported publicly, in accordance with the statute. This method provides all stakeholders with important information on healthcare provider quality, and in turn, relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets without directly influencing payment from CMS. One important consideration is to assess differential impact on IPFs, such as those located in rural, or critical access areas, to ensure that reporting does not disadvantage already resource-limited

settings. The type of reporting chosen by programs will depend on the program context.

Regardless of the methods used to report results, it is important to report stratified measure data alongside overall measure results. Review of both measures results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between healthcare providers and promote improvement for all patients, but unless stratified results are available, it is unclear if there are subgroups of patients that benefit most from initiatives. Notably, even if overall quality measure scores improve, without identifying and measuring differences in outcomes between groups of patients, it is impossible to track progress in reducing disparity for patients with heightened risk of poor outcomes.

B. Approaches to Assessing Drivers of Healthcare Quality Disparities and Developing Measures of Healthcare Equity in the IPFQR Program

This section presents information on two approaches for the IPFQR Program. The first section presents information about a method that could be used to assist IPFs in identifying potential drivers of healthcare quality disparities. The second section describes measures of health equity that might be appropriate for inclusion in the IPFQR Program.

a. Performance Disparity Decomposition

In response to the FY 2022 IPF PPS proposed rule's RFI (86 FR 19494 through 19500), ''Closing the Health Equity Gap in CMS Quality Programs,'' some stakeholders noted that identifying which factors are contributing to the performance gaps may not always be straightforward, especially if the IPF has limited information or resources to determine the extent to which a patient's driver of health or other mediating factors (for example: health histories) explain a given disparity. An additional complicating factor is the reality that there are likely multiple social determinants of health (SDOH) and other mediating factors responsible for a given disparity, and it may not be obvious to the IPF which of these factors are the primary drivers.

Consequently, CMS may consider methods to use the data already available in enrollment, claims, and assessment data to estimate the extent to which various SDOH (for example, transportation, health literacy) and other mediating factors drive disparities in an effort to provide more actionable information. Researchers have utilized decomposition techniques to examine inequality in health care and, specifically, as a way to understand and explain the underlying causes of inequality.[29] At a high level, regression decomposition is a method that allows one to estimate the extent to which disparities (that is, differences) in measure performance between subgroups of patient populations are due to specific factors. These factors can be either non-clinical (for example, SDOH) or clinical. Similarly, CMS may utilize regression decomposition to identify and calculate the specific contribution of SDOHs and other mediating factors to observed disparities. This approach may better inform our understanding of the extent to which providers and policy-makers may be able to narrow the gap in healthcare outcomes. Additionally, provider-specific decomposition results could be shared through confidential results so that IPFs can see the disparities within their facility with more granularity, allowing them to set priority targets in some performance areas while knowing which areas of their care are already relatively equitable. Importantly, these results could help IPFs identify reasons for disparities that might not be obvious without having access to additional data sources (for example: the ability to link data across providers).

To more explicitly demonstrate the types of information that could be provided through decomposition of a measure disparity, consider the following example for a given IPF. Figures 1 through 3 depict an example (using hypothetical data) of how a disparity in a measure of Medicare Spending Per Beneficiary (MSPB) between dual eligible beneficiaries (that is, those enrolled in Medicare and Medicaid) and non-dual eligible beneficiaries (that is, those with Medicare only) could be decomposed among two mediating factors, one SDOH and one clinical factor: (1) low health literacy and (2) high volume of emergency department (ED) use. These examples were selected because they are factors the healthcare provider could mitigate the effects of, if they were shown to be drivers of disparity in their IPF. Additionally, high volume ED use is used as a potential mediating factor that could be difficult for IPFs to determine on their own, as it will require having longitudinal data for patients across multiple facilities.

In Figure 1, the overall Medicare spending disparity is $1,000: spending, on average, is $5,000 per non-dual beneficiary and $6,000 per dual beneficiary. We can also see from Figure 2 that in this IPF, the dual population has twice the prevalence of beneficiaries with low health literacy and high ED use compared to the non-dual population. Using regression techniques, the difference in overall spending between non-dual and dual beneficiaries can be divided into three causes: (1) a difference in the prevalence of mediating factors (for example: low health literacy and high ED use) between the two groups; (2) a difference in how much spending is observed for beneficiaries with these mediating factors between the two groups; and (3) differences in baseline spending that are not due to either (1) or (2). In Figure 3, the 'Non-Dual Beneficiaries' column breaks down the overall spending per non-dual beneficiary, $5,000, into a baseline spending of $4,600 plus the effects of the higher spending for the 10 percent of non-dual beneficiaries with low health literacy ($300) and the 5 percent with high ED use ($100). The 'Dual Beneficiaries' column similarly decomposes the overall spending per dual beneficiary ($6,000) into a baseline spending of $5,000, plus the amounts due to dual beneficiaries' 20 percent prevalence of low health literacy ($600, twice as large as the figure for non-dual beneficiaries because the prevalence is twice as high), and dual beneficiaries' 10 percent prevalence of high-volume ED use ($200, similarly twice as high as for non-duals beneficiaries due to higher prevalence). This column also includes an additional $100 per risk factor because dual beneficiaries experience a higher cost than non-dual beneficiaries within the low health literacy risk factor, and similarly within the high ED use risk factor. Based on this information, an IPF can determine that the overall $1,000 disparity can be divided into differences simply due to risk factor prevalence ($300 + $100 = $400 or 40 percent of the total disparity), disparities in costs for beneficiaries with risk factors ($100 + $100 = $200 or 20 percent) and disparities that remain unexplained (differences in baseline costs: $400 or 40 percent).

In particular, the IPF can see that simply having more patients with low

[29] Rahimi E, Hashemi Nazari S. A detailed explanation and graphical representation of the Blinder-Oaxaca decomposition method with its application in health inequalities. *Emerg Themes Epidemiol.* (2021)18:12. *https://doi.org/10.1186/s12982-021-00100-9.* Retrieved 2/24/2022.

health literacy and high ED use accounts for a disparity of $400. In addition, there is still a $200 disparity stemming from differences in costs between non-dual and dual patients for a given risk factor, and another $400 that is not explained by either low health literacy or high ED use. These differences may instead be explained by other SDOH that have not yet been included in this breakdown, or by the distinctive pattern of care decisions made by providers for dual and non-dual beneficiaries. These cost estimates will provide additional information that facilities could use when determining where to devote resources aimed at achieving equitable health outcomes (for example, facilities may choose to focus efforts on the largest drivers of a disparity).

Figure 1

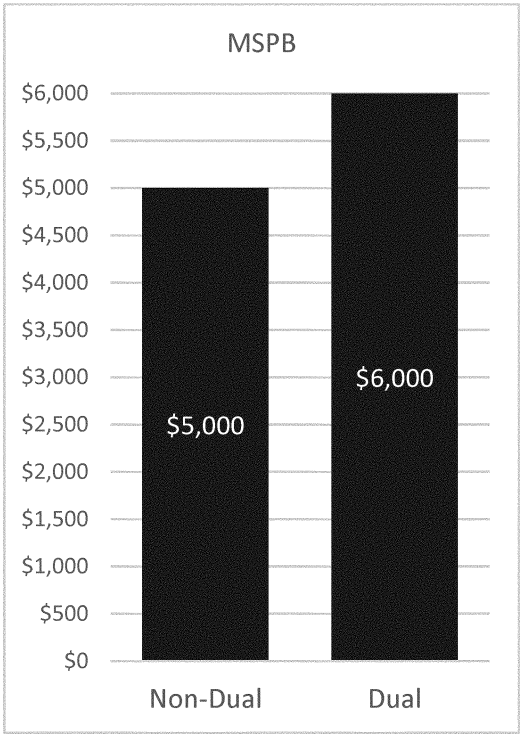


Figure 2

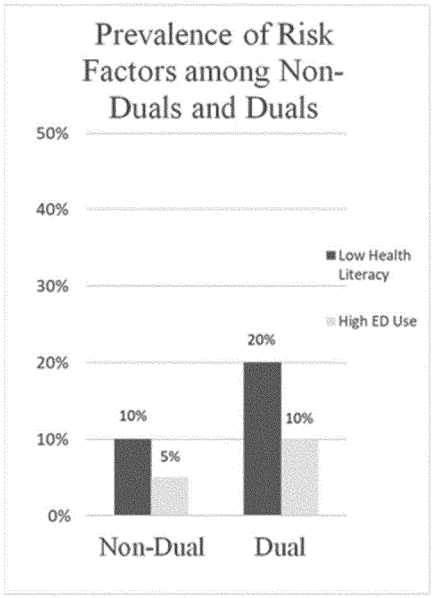
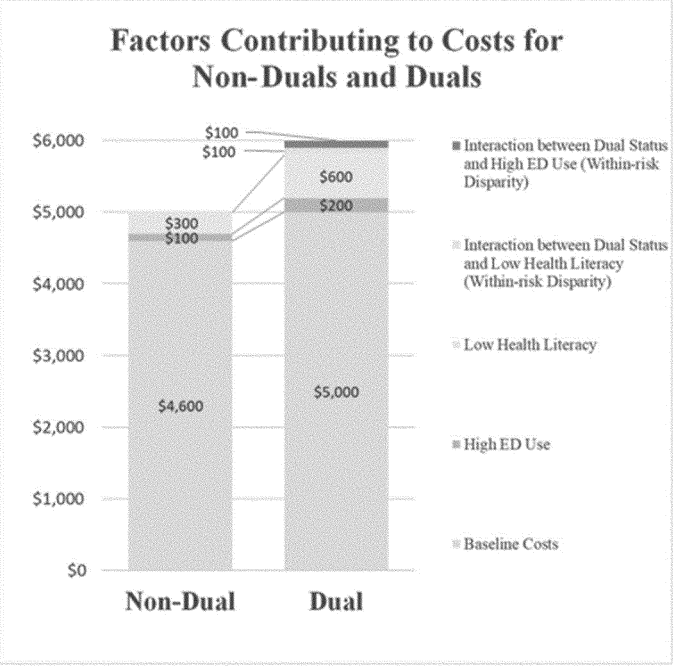


Figure 3



b. Measures Related to Health Equity

Beyond identifying disparities in individual health outcomes and by individual risk factors, there is interest in developing more comprehensive measures of health equity that reflect organizational performance. When determining which equity measures could be prioritized for development for the IPFQRP Program, CMS may consider the following:

- Measures should be actionable in terms of quality improvement;
- Measures should help beneficiaries and their caregivers make informed healthcare decisions;
- Measures should not create incentives to lower the quality of care; and
- Measures should adhere to high scientific acceptability standards.

CMS has developed measures assessing health equity, or designed to promote health equity, in other settings outside of the IPF. As a result, there may be measures that could be adapted for use in the IPFQR Program. The remainder of this section discusses two such measures, beginning with the Health Equity Summary Score (HESS), and then a structural measure assessing the degree of hospital leadership engagement in health equity performance data.

(1) Health Equity Summary Score

The HESS measure was developed by the CMS OMH [30] [31] to identify and to reward healthcare providers (that is, Medicare Advantage [MA] plans) that perform relatively well on measures of care provided to beneficiaries with social risk factors (SRFs), as well as to discourage the non-treatment of patients who are potentially high-risk, in the context of value-based purchasing. Additionally, a version of the HESS is under consideration for the Hospital Inpatient Quality Reporting (HIQR) program.[32] The HESS composite measure provides a summary of equity of care delivery by combining performance and improvement across multiple measures and multiple at-risk groups. The HESS was developed with the following goals: allow for ''multiple grouping variables, not all of which will be measurable for all plans,'' allow for ''disaggregation by grouping variable for nuanced insights,'' and allow for the future usage of additional and different SRFs for grouping.[33]

The HESS computes across-provider disparity in performance, as well as within-provider and across-provider disparity improvement in performance. Calculation starts with a cross-sectional score and an overall improvement score for each SRF of race/ethnicity and dual eligibility, for each plan. The overall improvement score is based on two separate improvement metrics: within-plan improvement and nationally benchmarked improvement. Within-plan improvement is defined as how that plan improves the care of patients with SRFs relative to higher-performing patients between the baseline period and performance period, and is targeted at eliminating within-plan disparities. Nationally benchmarked improvement is improvement of care for beneficiaries with SRFs served by that MA plan, relative to the improvement of care for similar beneficiaries across all MA plans, and is targeted at improving the overall care of populations with SRFs. Within-plan improvement and nationally benchmarked improvement are then combined into an overall

[30] Agniel D., Martino S.C., Burkhart Q., Hambarsoomian K., Orr N., Beckett M.K., James C., Scholle S.H., WilsonFrederick S., Ng J., Elliott M.N. (2021). Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med, 36(7):1847–1857. doi: 10.1007/s11606–019–05473-x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at *https://link.springer.com/content/pdf/10.1007/s11606-019-05473-x.pdf.* Accessed February 3, 2022.

[31] 2021 Quality Conference. Health Equity as a ''New Normal'': CMS Efforts to Address the Causes of Health Disparities. Available at *https://s3.amazonaws.com/bizzabo.file.upload/83kO1DYXTs6mKHjVtuk8_1%20-%20Session%2023%20Health%20Equity%20New%20Normal%20FINAL_508.pdf.* Accessed March 2, 2022.

[32] Centers for Medicare & Medicaid Services, FY 2022 IPPS/LTCH PPS Proposed Rule. 88 FR 25560. May 10, 2021.

[33] Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH). 2021b. ''Health Equity as a 'New Normal': CMS Efforts to Address the Causes of Health Disparities.'' Presented at CMS Quality Conference, March 2–3, 2021.

improvement score. Meanwhile, the cross-sectional score measures overall measure performance among beneficiaries with SRFs during the performance period, regardless of improvement.

To calculate a provider's overall score, the HESS uses a composite of five clinical quality measures based on HEDIS data and seven MA Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient experience measures. A provider's overall HESS score is calculated once using only CAHPS-based measures and once using only HEDIS-based measures, due to incompatibility between the two data sources. The HESS uses a composite of these measures to form a cross-sectional score, a nationally benchmarked improvement score, and a within-plan improvement score, one for each SRF. These scores are combined to produce an SRF-specific blended score, which is then combined with the blended score for another SRF to produce the overall HESS.

(2) Degree of Hospital Leadership Engagement in Health Equity Performance Data

CMS has developed a structural measure for use in acute care hospitals assessing the degree to which hospital leadership is engaged in the collection of health equity performance data, with the motivation that organizational leadership and culture can play an essential role in advancing equity goals. This structural measure, entitled the Hospital Commitment to Health Equity measure (MUC2021–106) was included on the 2021 CMS List of Measures Under Consideration (MUC List) [34] for acute inpatient hospitals and assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. The measure would include five attestation-based questions, each representing a separate domain of commitment. A hospital would receive a point for each domain where they attest to the corresponding statement (for a total of 5 points). At a high level, the five domains cover the following areas: (1) strategic plan to reduce health disparities; (2) approach to collecting valid and reliable demographic and SDOH data; (3) analyses performed to assess disparities; (4) engagement in quality improvement activities; [35] and (5) leadership involvement in activities designed to reduce disparities. The specific questions requested within each domain, as well as the detailed measure specification are found in the CMS MUC List for December 2021 at *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.* A hospital could receive a point for each domain where data are submitted through a CMS portal to reflect actions taken by the hospital for each corresponding domain (for a point total). If we were to consider this measure for the IPFQR Program, we would include it for this program on a future MUC list.

CMS believes this type of organizational commitment structural measure may complement the health disparities approach described in previous sections, and support IPFs in quality improvement, efficient, effective use of resources, and leveraging available data. As defined by AHRQ, structural measures aim to ''give consumers a sense of a healthcare provider's capacity, systems, and processes to provide high-quality care.'' [36] We acknowledge that collection of this structural measure may impose administrative and/or reporting requirements for IPFs.

We requested feedback from stakeholders on conceptual and measurement priorities for the IPFQR Program to better illuminate organizational commitment to health equity.

C. Solicitation of Public Comment

We requested information with the goal to describe key principles and approaches that we will consider when advancing the use of quality measure development and stratification to address healthcare disparities and advance health equity across our programs.

We invited general comments on the principles and approaches described previously in this section of the rule, as well as additional thoughts about disparity measurement or stratification guidelines suitable for overarching consideration across CMS' QRP programs. Specifically, we invited comment on:

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs
  - ++ The use of the within- and between-provider disparity methods in IPFs to present stratified measure results
  - ++ The use of decomposition approaches to explain possible causes of measure performance disparities
  - ++ Alternative methods to identify disparities and the drivers of disparities
- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting
  - ++ Principles to consider for prioritization of health equity measures and measures for disparity reporting, including prioritizing stratification for validated clinical quality measures, those measures with established disparities in care, measures that have adequate sample size and representation among healthcare providers and outcomes, and measures of appropriate access and care.
- Principles for Social Risk Factor and Demographic Data Selection and Use
  - ++ Principles to be considered for the selection of social risk factors and demographic data for use in collecting disparity data including the importance of expanding variables used in measure stratification to consider a wide range of social risk factors, demographic variables and other markers of historic disadvantage. In the absence of patient-reported data we will consider use of administrative data, area-based indicators and imputed variables as appropriate
- Identification of Meaningful Performance Differences
  - ++ Ways that meaningful difference in disparity results should be

[34] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2021. Available at *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.* Accessed 3/1/2022.

[35] As described in our guide to quality measurement and quality improvement, the National Academy of Medicine defines quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Quality improvement is the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital; process includes knowledge capital (for example, standard operating procedures) or human capital (for example, education and training). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement—*. Accessed 3/1/2022.

[36] Agency for Healthcare Research and Quality. Types of Health Care Quality Measures. 2015. Available at *https://www.ahrq.gov/talkingquality/measures/types.html.* Accessed February 3, 2022.

considered.
- Guiding Principles for Reporting Disparity Measures
  - ++ Guiding principles for the use and application of the results of disparity measurement.
- Measures Related to Health Equity
  - ++ The usefulness of a HESS score for IPFs, both in terms of provider actionability to improve health equity, and in terms of whether this information would support Care Compare website users in making informed healthcare decisions.
  - ++ The potential for a structural measure assessing an IPF's commitment to health equity, the specific domains that should be captured, and options for reporting this data in a manner that would minimize burden.
  - ++ Options to collect facility-level information that could be used to support the calculation of a structural measure of health equity.
  - ++ Other options for measures that address health equity.

Consistent with what we stated in the proposed rule, we will not be responding to specific comments submitted in response to this RFI in this final rule, we will actively consider all input as we develop future policies that address these issues. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary. Below is a summary of the comments we received in response to this request for information.

We received the following comments in response to our request for information.

Comment: Many commenters expressed support for reporting stratified IPF measures, specifically recommending providing these data in confidential reports prior to public reporting. Some commenters described potential benefits of public reporting including improved transparency, increased provider accountability, and use of market forces to drive improvement. Several commenters provided recommendations for developing a stratified reporting strategy, including focusing on data that cannot be calculated independently by IPFs, providing support to the public in interpreting the data, and analyzing the effects of potential confounders when developing reports. One commenter recommended that IPFs only be compared to other IPFs in between-provider analyses.

Some commenters expressed concerns regarding stratified data reporting. One commenter expressed that publicly reported stratified data could lead to the perception that it is acceptable for some subgroups to experience worse care. This commenter recommended the use of performance benchmarks or national thresholds instead of the between-provider disparity method. Several commenters expressed concern that the burden of collecting data for stratifying the chart-based measure outweighs the potential benefit of stratifying these measures, especially given small numbers of patients in each stratum and high overall performance on the measures. Some of these commenters specifically stated that IPFs do not have widespread electronic health technology to support this data collection. Several commenters were concerned that there may be unintended consequences of reporting data based on a small sample and recommended that CMS establish a minimum sample size for subgroup reporting. Another commenter recommended using estimates of variability (that is, confidence intervals) when reporting data. Another commenter observed that while stratification of claims-based measures is less burdensome, this reporting would exclude patients with private insurance coverage and rely on data, which are not self-reported. Some commenters recommended that CMS analyze the predictive power of drivers of health compared to the predictive power of the diagnosis requiring treatment prior to stratifying any measures by drivers of health. Another commenter recommended further analysis of regression decomposition prior to considering this technique in data reporting. Some commenters expressed that stratification based on dual-eligibility creates bias due to state-level variation in Medicaid eligibility. One commenter recommended stratifying based on eligibility for the low-income subsidy (LIS) instead. One commenter cautioned CMS to ensure patient privacy is safeguarded, especially when reporting on small samples.

Many commenters expressed support for the collection of data (including race, ethnicity, language, and other factors) to support increased reporting of stratified data, though these commenters observed that there are not currently industry standards for most of these data and recommended developing standard terminology prior to proceeding. One commenter expressed that this data collection could improve provider interventions and performance in providing care. Some commenters recommended that CMS partner with other entities such as states and private payors to align data collection requirements. Some commenters recommended that CMS evaluate use of claims to identify drivers of health, such as by using payment programs to incentive the use of ICD–10 Z Codes. One commenter observed that if CMS were to adopt a patient experience of care measure in this setting the same collection instrument could be used to collect self-reported demographic data. Other commenters supported use of proxy variables, such as indices or other data sets, when self-reported data are unavailable. Some commenters supported further research into statistical imputation prior to use in stratification.

Many commenters expressed concerns about potentially adapting the HESS for this setting. Some commenters observed that an aggregated score may not be actionable for many facilities, with one commenter recommending only reporting such a measure with all its component scores. One commenter cautioned that in using a composite score a single risk factor could mask the effects of other risk factors. Another commenter stated that HESS scoring may not be practical for many smaller facilities, or facilities whose enrolled populations differ in drivers of health distribution patterns compared to typical MA plans. Several commenters expressed the belief that the measures underlying the HESS (HEDIS and CAHPS) are not applicable for the IPF settings. Another commenter observed that calculation of a HESS-type measure would require standardized demographic data collection for all patients. One commenter recommended that if CMS were to develop a summary measure for quality reporting programs for settings other than IPFs, it should include behavioral health measures in the composite because socially at-risk groups often experience poor mental health outcomes.

Many commenters supported the Degree of Hospital Leadership Engagement in Health Equity Performance Data measure concept. Some of these commenters recommended that CMS adopt this structural measure before process or outcome measures related to health equity. However, several commenters provided recommendations or expressed concerns about this measure. Several commenters observed that the measure as specified would be difficult for many IPFs to report due to the requirement to use certified electronic health record technology (CEHRT). One commenter expressed that there is no evidence that performance on this

measure is associated with improved patient outcomes. One commenter recommended adopting an audit procedure along with this measure. Another commenter recommended adding a different attestation measure on other efforts to gauge hospital data collection efforts (for example, the Leapfrog Hospital Survey).

Many commenters observed that there are measures of patient experience of care for other settings and that having such a measure in the IPF setting would improve public accountability and quality of care. A few commenters stated that a patient experience of care measure is necessary to improve the equity of care provided by IPFs.

Several commenters stated that improving health equity would require government investment in addressing social needs, such as reducing financial barriers to access. One commenter observed that having such an investment would reduce provider frustration with data collection requirements.

Several commenters recommended linking payment to equity performance; these commenters specifically recommended the use of incentives to avoid unintended consequences for socially at-risk patients. One commenter recommended the use of peer grouping (that is, comparing each provider's performance with providers with similar mixes of patients, that is, its ''peers,'' to determine rewards or penalties based on performance) within value based purchasing (VBP) programs.

Several commenters supported the suggested criteria for prioritizing equity measures and recommended additional criteria including building on existing health equity strategies, balancing administrative burden, allowing flexibility, relying on existing data sources, relying on measures that include self-reported data in the measure structure, providing timely feedback, expanding to include resource use measures, and aligning with states and other payors.

Some commenters provided general feedback on the concept of using quality reporting programs to reduce healthcare disparities. Several commenters observed that quality improvement initiatives are often initiated at the system level and therefore measurement should be at the system level to avoid duplicative reporting requirements. Another commenter expressed the belief that it would be appropriate to update the conditions of participation to address health equity. Other commenters recommended that any effort to use quality reporting to reduce healthcare disparities should include detailed definitions of all variables (for example, health outcomes, hospital leadership).

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We note that in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed several measures related to health equity for the Hospital Inpatient Quality Reporting (IQR) program. Specifically, we proposed the Hospital Commitment to Health Equity measure (87 FR 28492 through 28497) and two social drivers of health measures (87 FR 28497 through 28506). and we may consider these or similar measures for other quality reporting programs, such as the IPFQR Program in the future. Additionally, we refer readers to the FY 2022 IPF PPS final rule in which we described our initial request for information on the concept of an equity summary score for the IPF setting and summarized the input we received (86 FR 42625 through 42632). We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts. If we determine that a measure, including a patient experience of care measure, a health equity measure, or any other measure is appropriate for the IPFQR program we will follow the pre-rulemaking process as described on our website (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking*).

For more information on our ongoing effort to address health equity, we refer readers to our recently released updated CMS Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*) and our Framework for Health Equity (*https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*) in which we describe our five priorities for advancing health equity.

VII. Collection of Information Requirements

This final rule updates the prospective payment rates, outlier threshold, and wage index for Medicare inpatient hospital services provided by IPFs. It also establishes a permanent mitigation policy for providers negatively affected by changes to the IPF PPS wage index. While discussed in section IV (Comment Solicitation on Analysis of IPF PPS Adjustments) of this preamble, the active requirements and burden associated with our hospital cost report form CMS–2552–10 (OMB control number 0938–0050) are unaffected by this rule.

Therefore, this document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VIII. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2023 (October 1, 2022 through September 30, 2023). We are finalizing our proposal to apply the 2016-based IPF market basket increase of 4.1 percent, less the productivity adjustment of 0.3 percentage point as required by section 1886(s)(2)(A)(i) of the Act for a total FY 2023 payment rate update of 3.8 percent. In this final rule, we are finalizing our proposal to update the outlier fixed dollar loss threshold amount, update the IPF labor-related share, and update the IPF wage index to reflect the FY 2023 hospital inpatient wage index. Lastly, for FY 2023 and subsequent years, we will apply a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2))

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and

equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). We estimate that the total impact of these changes for FY 2023 payments compared to FY 2022 payments will be a net increase of approximately $90 million. This reflects a $130 million increase from the update to the payment rates (+$140 million from the second quarter 2022 IGI forecast of the 2016-based IPF market basket of 4.1 percent, and −$10 million for the productivity adjustment of 0.3 percentage point), as well as a $40 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 3.2 percent in FY 2022 to 2.0 percent of total estimated IPF payments in FY 2023.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a ''major'' rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

In this section, we discuss the historical background of the IPF PPS and the impact of this final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. This budget neutrality factor included the following components: outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section IV.D.1 of this final rule, we are updating the wage index and labor-related share, as well as applying the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, in a budget neutral manner, by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT payment per treatment. Therefore, the budgetary impact to the Medicare program of this final rule will be due to the market basket update for FY 2023 of 4.1 percent (see section IV.A.2 of this final rule) less the productivity adjustment of 0.3 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2023 impact will be a net increase of $90 million in payments to IPF providers. This reflects an estimated $130 million increase from the update to the payment rates and a $40 million decrease due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2023. This estimate does not include the implementation of the required 2.0 percentage point reduction of the productivity-adjusted market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section IV.B.2. of this final rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final rule, we compare estimated payments under the IPF PPS rates and factors for FY 2023 versus those under FY 2022. We determined the percent change in the estimated FY 2023 IPF PPS payments compared to the estimated FY 2022 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data including the labor-related share and the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year; and the market basket update for FY 2023, as reduced by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act. To illustrate the impacts of the FY 2023 changes in this final rule, our analysis begins with FY 2021 IPF PPS claims (based on the 2021 MedPAR claims, March 2022 update). As discussed in section IV.E.2 of this final rule, we are excluding providers from our impact simulations whose change in estimated cost per day is outside 3 standard deviations from the mean. We estimate FY 2022 IPF PPS payments using these 2021 claims, the finalized FY 2022 IPF PPS Federal per diem base rates, and the finalized FY 2022 IPF PPS patient and facility level adjustment factors (as published in the FY 2022 IPF PPS final rule (86 FR 42608)). We then estimate the FY 2022 outlier payments based on these simulated FY 2022 IPF PPS payments using the same methodology as finalized in the FY 2022 IPF PPS final rule (86 FR 42623 through 42624) where total outlier payments are maintained at 2 percent of total estimated FY 2022 IPF PPS payments. Each of the following changes is added incrementally to this baseline model in order to isolate the effects of each change:

- The final update to the outlier fixed dollar loss threshold amount.
- The final FY 2023 IPF wage index, the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and the FY 2023 labor-related share.
- The final market basket update for FY 2023 of 4.1 percent less the productivity adjustment of 0.3 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 3.8 percent.

Our column comparison in Table 3 illustrates the percent change in payments from FY 2022 (that is, October 1, 2021, to September 30, 2022) to FY 2023 (that is, October 1, 2022, to September 30, 2023) including all the payment policy changes.

TABLE 3: FY 2023 IPF PPS PAYMENT IMPACTS

[Percent Change in columns 3 through 5]

Facility by Type	Number of Facilities	Outlier	FY 2023 Wage Index (with cap) and LRS	Total Percent Change[1]
(1)	(2)	(3)	(4)	(5)
All Facilities	1,417	-1.2	0.0	2.5
Total Urban	1,150	-1.3	0.0	2.5
Urban unit	673	-2.0	0.0	1.7
Urban hospital	477	-0.5	0.1	3.4
Total Rural	267	-0.7	-0.2	2.9
Rural unit	210	-0.8	-0.1	2.8
Rural hospital	57	-0.5	-0.3	3.0
By Type of Ownership:				
Freestanding IPFs				
Urban Psychiatric Hospitals				
Government	116	-1.9	0.2	2.0
Non-Profit	94	-0.8	0.3	3.2
For-Profit	267	-0.1	0.0	3.7
Rural Psychiatric Hospitals				
Government	30	-0.7	-0.4	2.7
Non-Profit	12	-1.6	-0.1	2.1
For-Profit	15	-0.1	-0.3	3.4
IPF Units				
Urban				
Government	91	-2.9	0.0	0.8
Non-Profit	443	-2.2	-0.1	1.5
For-Profit	139	-1.0	0.1	2.9
Rural				
Government	46	-0.7	0.0	3.1
Non-Profit	123	-1.0	-0.2	2.6
For-Profit	41	-0.4	-0.1	3.2
By Teaching Status:				
Non-teaching	1,228	-1.0	0.1	2.8
Less than 10% interns and residents to beds	100	-1.6	-0.2	2.0
10% to 30% interns and residents to beds	62	-3.4	-0.4	0.0
More than 30% interns and residents to beds	27	-3.3	0.2	0.6
By Region:				
New England	101	-1.8	-0.5	1.4
Mid-Atlantic	183	-1.7	0.1	2.1
South Atlantic	220	-0.7	-0.3	2.8
East North Central	232	-1.1	-0.4	2.3

East South Central	140	-0.8	-0.2	2.8
West North Central	102	-1.9	-0.2	1.6
West South Central	213	-0.5	0.4	3.7
Mountain	100	-0.8	0.0	3.0
Pacific	126	-1.8	0.8	2.7
By Bed Size:				
Psychiatric Hospitals				
Beds: 0-24	83	-0.6	0.2	3.4
Beds: 25-49	78	-0.2	0.1	3.7
Beds: 50-75	79	-0.2	-0.1	3.5
Beds: 76 +	294	-0.6	0.0	3.2
Psychiatric Units				
Beds: 0-24	483	-1.4	0.0	2.3
Beds: 25-49	234	-1.7	0.0	2.0
Beds: 50-75	102	-2.4	-0.1	1.2
Beds: 76 +	64	-2.3	0.0	1.3

[1] This column includes the impact of the updates in columns (3) through (4) above, and of the final IPF market basket update factor for FY 2023 (4.1 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Impact Results

Table 3 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services file, the IPF PSF, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.
- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,417 IPFs included in the analysis. In column 2, we present the number of facilities of each type that had information available in the PSF, had claims in the MedPAR dataset for FY 2021, and were not excluded due to the trim on providers whose change in estimated cost per day is outside 3 standard deviations from the mean.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 3.2 percent in FY 2022. Therefore, we adjusted the outlier threshold amount to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2023. The estimated change in total IPF payments for FY 2023, therefore, includes an approximate 1.2 percent decrease in payments because we expect the outlier portion of total payments to decrease from approximately 3.2 percent to 2.0 percent.

The overall impact of the estimated decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 3), across all hospital groups, is a 1.2 percent decrease. The largest decrease in payments due to this change is estimated to be 3.4 percent for teaching IPFs with 10 percent to 30 percent interns and residents to beds.

In column 4, we present the effects of the budget-neutral update to the IPF wage index, the labor-related share (LRS), and the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year discussed in section IV.D.2 of this final rule. This represents the effect of using the concurrent hospital wage data as discussed in section IV.D.1.a of this final rule. That is, the impact represented in this column reflects the update from the FY 2022 IPF wage index to the FY 2023 IPF wage index, which includes basing the FY 2023 IPF wage index on the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index data, applying a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and updating the LRS from 77.2 percent in FY 2022 to 77.4 percent in FY 2023. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4; however, there are distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 0.8 percent for Pacific IPFs, and the largest decrease in payments to be 0.5 percent for New England IPFs.

Overall, IPFs are estimated to experience a net increase in payments of 2.5 percent as a result of the updates in this final rule. IPF payments are therefore estimated to increase by 2.5 percent in urban areas and 2.9 percent in rural areas. The largest payment increases are estimated at 3.7 percent for freestanding urban for-profit IPFs, IPFs located in the West South Central region, and IPF hospitals with 25 to 49 beds.

4. Effect on Beneficiaries

Under the FY 2023 IPF PPS, IPFs will continue to receive payment based on the average resources consumed by patients for each day. Our longstanding payment methodology reflects the differences in patient resource use and costs among IPFs, as required under section 124 of the BBRA. We expect that updating IPF PPS rates in this final rule will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in inpatient psychiatric care and the costs of these resources. We continue to expect that paying prospectively for IPF services under the FY 2023 IPF PPS will enhance the efficiency of the Medicare program.

5. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this

final rule, we estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of this final rule. For the FY 2023 IPF PPS final rule, the most recent IPF proposed rule was the FY 2023 IPF PPS proposed rule, and we received 396 unique comments on this proposed rule. We believe that the number of past commenters on the most recent IPF proposed rule would be a fair estimate of the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2023 IPF PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. We solicited comments on this assumption and did not receive any comments on it.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Using the May 2021 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $115.22 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes119111*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 64 minutes (1.07 hours) for the staff to review half of this final rule, which contains a total of approximately 32,000 words. For each IPF that reviews the final rule, the estimated cost is $123.29 (1.07 × $115.22). Therefore, we estimate that the total cost of reviewing this final rule is $48,822.84 ($123.29 × 396 reviewers).

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. We continue to believe it is appropriate to routinely update the IPF PPS so that it reflects the best available data about differences in patient resource use and costs among IPFs as required by the statute. Therefore, we are finalizing our proposal to update the IPF PPS using the methodology published in the November 2004 IPF PPS final rule; applying the 2016-based IPF PPS market basket update for FY 2023 of 4.1 percent, reduced by the statutorily required productivity adjustment of 0.3 percentage point along with the wage index budget neutrality adjustment to update the payment rates; and finalizing a FY 2023 IPF wage index which uses the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index as its basis. Additionally, we are applying a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. Lastly, we are excluding providers from our simulation of IPF PPS payments for FY 2022 and FY 2023 if their change in estimated cost per day is outside 3 standard deviations from the mean.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table 4, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF wage index and payment rates in this final rule. Table 4 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,417 IPFs with data available in the PSF, with claims in our FY 2021 MedPAR claims dataset, and which were not excluded due to the trim on providers whose change in estimated cost per day is outside 3 standard deviations from the mean. Lastly, Table 4 also includes our best estimate of the costs of reviewing and understanding this final rule.

TABLE 4: Accounting Statement: Classification of Estimated Costs, Savings, and Transfers

Category	Primary estimate ($million/year)	Units	
		Year dollars	Period covered
Regulatory Review Costs	0.05	FY 2021	FY 2023
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	90	FY 2023	FY 2023

F. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of $8 million to $41.5 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs' revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 3, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by approximately 2.5 percent. As a result, the estimated impact of this final rule is a net increase in revenue across almost all categories of IPFs. Therefore, the Secretary has determined that this final rule will have a positive revenue impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis

must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section VIII.C.2 of this final rule, the rates and policies set forth in this rule will not have an adverse impact on the rural hospitals based on the data of the 210 rural excluded psychiatric units and 57 rural psychiatric hospitals in our database of 1,417 IPFs for which data were available. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This final rule will not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $165 million in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule does not impose substantial direct costs on state or local governments or preempt state law.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 25, 2022.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 412 as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.424 is amended by revising paragraph (d)(1)(i) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(i) *Adjustment for wages.* CMS adjusts the labor portion of the Federal per diem base rate to account for geographic differences in the area wage levels using an appropriate wage index.

(A) The application of the wage index is made on the basis of the location of the inpatient psychiatric facility in an urban or rural area as defined in § 412.402.

(B) Beginning October 1, 2022, CMS applies a cap on decreases to the wage index, such that the wage index applied to an inpatient psychiatric facility is not less than 95 percent of the wage index applied to that inpatient psychiatric facility in the prior fiscal year.

* * * * *

Dated: July 25, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–16260 Filed 7–27–22; 4:15 pm]

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FEDERAL REGISTER

Vol. 87 Friday,
No. 145 July 29, 2022

Part IV

The President

Notice of July 28, 2022—Continuation of the National Emergency With Respect to Lebanon

Federal Register
Vol. 87, No. 145
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Presidential Documents

Title 3—

The President

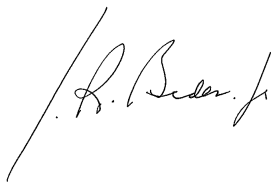
Notice of July 28, 2022

Continuation of the National Emergency With Respect to Lebanon

On August 1, 2007, by Executive Order 13441, the President declared a national emergency with respect to Lebanon pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of certain persons to undermine Lebanon's legitimate and democratically elected government or democratic institutions; to contribute to the deliberate breakdown in the rule of law in Lebanon, including through politically motivated violence and intimidation; to reassert Syrian control or contribute to Syrian interference in Lebanon; or to infringe upon or undermine Lebanese sovereignty. Such actions contribute to political and economic instability in that country and the region.

Certain ongoing activities, such as Iran's continuing arms transfers to Hizballah—which include increasingly sophisticated weapons systems—serve to undermine Lebanese sovereignty, contribute to political and economic instability in the region, and continue to constitute an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on August 1, 2007, must continue in effect beyond August 1, 2022. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Lebanon declared in Executive Order 13441.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 28, 2022.

[FR Doc. 2022–16516
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